

Market Research Services Relative to Updating the Medicare Physician Fee Schedule Direct Practice Expense Inputs

**U.S. Department of Health and
Human Services**

Centers for Medicare and Medicaid Services

Direct Practice Expense Input Market Research Report

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SUBMITTED BY:

StrategyGen
10320 Little Patuxent Parkway, Suite 200
Columbia, MD 21044
StrategyGen.com

Direct Practice Expense Input Market Research Report

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Executive Summary

Background: Since 1992 Medicare has paid for physician services as required by §1848 of the Social Security Act (Act). The Medicare Physician Fee Schedule (PFS) reimburses physicians and other eligible providers for professional services furnished to Medicare beneficiaries using a resource based relative value system (RBRVS) that accounts for the physician work, the practice expense, and the malpractice expense incurred in providing each service. PFS reimbursement is further adjusted for geographic cost variations. In 2015, Medicare paid for more than one billion distinct services under the PFS.

Section 220(a) of the Protecting Access to Medicare Act of 2014 provides that the Centers for Medicare and Medicaid Services (CMS) may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of practice expense inputs; overhead and accounting information from practices of physicians and other suppliers, and any other elements that would improve the accuracy of the valuation of services under the PFS.

Within the RBRVS, the practice expense (PE) component seeks to capture physician practice expenses, such as office rent and personnel wages (excluding malpractice expenses) as specified in section 1848(c)(1)(B) of the Act. PE accounts for an average of 45% of the total relative value units (RVUs) for a professional service and thus has a significant impact on physician reimbursement under the PFS.

The purpose of this market research report is to provide pricing recommendations for the medical equipment and supplies found in the Medicare Physician Fee Schedule Direct Practice Expense Inputs (DPEI). Additionally, this report documents the methodology used to develop these pricing recommendations.

Materials and Methods: The recommendations contained in this report were developed by a work team comprised of market researchers, regulatory attorneys, physicians, PhDs, a biostatistician, and health policy experts, who conducted robust market research and analysis to develop pricing recommendations for updating the PFS DPEI. Reliable and valid primary and secondary market research resources and methodologies were employed to estimate and validate current prices for medical equipment and medical supplies. Market research methodologies included telephone surveys, aggregate databases reviews, vendor interviews, market scans, market analysis, physician substantiation, and statistical analysis.

Secondary market research was conducted on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The secondary resources used to gather price data and other information included:

1. Aggregate health system provider databases, which included information on price discounts where applicable (Buyers);
2. Publicly available vendor resources, i.e., Amazon Business, Cardinal Health (Vendors);
3. The General Services Administration Schedule (GSA); and
4. Federal Register, current DPEI data, historic proposed and final rules prior to and including FY2018, and other resources, such as the RVS Update Committee of the American Medical Association (see References).

Research of equipment and supply items was prioritized based on the total volume of CMS spending (Total Spend). While all items were examined using secondary research tools, primary research was conducted on items of equipment and supply with the greatest Total Spend, prioritized by the amount spent by CMS in the last reported fiscal year. The following primary research resources were employed:

1. Telephone surveys with vendors (Vendor Surveys) for Top (as defined herein) priority items;
2. Physician panel (Physician Panel) validation of selected market research results; and
3. Analysis by subject matter experts, including experts in the healthcare regulatory environment, health care policy, market research, and statistical analysis.

Key Research Findings:

- On average, commercial prices for medical equipment and supplies are relatively consistent with the prices in the DPEI, which prices are generally based on historical invoices. No statistically significant difference was identified between the average of current CMS prices and the average of market research-based commercial prices identified by this study.
- Commercial prices of certain individual items of equipment and supply varied significantly.
- Commercial prices of certain equipment and supplies were found to vary substantially from the current CMS DPEI prices.
- Discounted prices for supplies are often tied to contracts for negotiated equipment discounts, through service contracts and group purchasing organization contracts. These multi-year purchasing contracts may be an important factor contributing to the price stability found in the market.

There are many possible explanations of why some of the current CMS prices may be higher than commercial market prices identified. For example, the market research captured prices net discounts,

rather than simply the posted retail price. It is possible that actual market prices may have decreased on some items over the last decade, or possibly the market for some items has changed in response to competition or other factors.

The overall average stable pricing for medical equipment and supplies does not imply that there were no price increases between the current CMS and researched commercial price. For example, technology advancements that have caused some historically high-priced equipment (i.e. desktop PCs) to be replaced by substantially less expensive technology (i.e. laptops and tablets) may be driving the overall stability of the market. However, much of the older less expensive technology is being replaced by similarly priced yet more sophisticated technology. Future research should include additional investigation into critical items where the market prices are materially lower than the historical Current CMS Prices to better understand the drivers of change for appropriate pricing.

Unlike the Commercial Price, the research did indicate a statistically significant difference between the ‘averages’ of the Current CMS Price and the GSA Price for equipment but not for supplies. While the GSA system by design provides the lowest available prices to government purchasers, the lack of data within the GSA system for many equipment codes also impacted the results. This lack of data may indicate that eligible providers typically use sources other than the GSA to purchase medical equipment or it may indicate that certain types of medical equipment are not frequently purchased by government entities. Various other explanations are also possible. For example, the vendor survey indicated that vendors most frequently offer discounts through multi-year contracts such as group purchasing and service agreements.

Data: This DPEI Market Research Report, as well as the following tables, are available in spreadsheet format:

1. Attachment A – DPEI Report Attached Table A represents the research results with Current CMS Prices, the Recommended CMS Prices, and GSA Prices.
2. Attachment B – DPEI Report Attached Table B includes the Recommended CMS Price and four (4) alternative pricing models.

Recommended CMS Price: The Recommended CMS Price for equipment and supply items is the researched-commercial price (when available) or the current CMS Commercial Price when researched-commercial data is unavailable. An in-depth analysis of the market research, health policy perspectives, and the evaluation of four other statistical models were used to substantiate the Recommended CMS Price for equipment and supply items (See Section 5).

Data Validity and Assumptions: This market research is based on reliable and robust primary and secondary research resources and methodologies, which were used to create recommended

prices for medical equipment and supplies for the CY 2019 Medicare Physician Fee Schedule DPEI. In-depth market research of commercial prices was conducted using the medical equipment and supply benchmark databases compiled by CMS from invoices and other information reported by providers. The provider benchmark data was combined with publicly available commercial pricing data.

This robust market research methodology for commercial prices resulted in a total sample size of 77,780 price points for equipment and more than 10,067 price points for supplies. There were 1,065 equipment price points and 3,293 supply price points were researched on the GSA system. On average, prices collected on equipment items from the provider benchmark database were drawn from transactions representing a 65% market share. Supply prices from the provider benchmark database were collected for the top three most frequently purchased items, as identified in purchase orders submitted by providers to the benchmark database.

Primary market research was conducted, surveying a total of ninety-four vendor representatives to obtain additional validation of market findings, trends and to provide contextual insights. Finally, a Physician Panel was used to review and to validate findings and to provide contextual insight.

1.0 Introduction

Since January 1, 1992, Medicare has paid for physician services under section 1848 of the Social Security Act (Act). The Medicare Physician Fee Schedule (PFS) reimburses physicians and other eligible providers for professional services based on a resource based relative value system (RBRVS) that assigns units of value for the physician work, the practice expense, and the malpractice expense incurred in providing each service. In 2015, Medicare paid for more than one billion distinct services under the PFS.

Section 220(a) of the Protecting Access to Medicare Act of 2014 provides that CMS may collect or obtain information from eligible professionals or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of practice expense inputs; overhead and accounting information collected from physicians and other suppliers, and any other elements that would improve the accuracy of valuing services under the PFS.

Under the PFS payment structure, practice expense (PE) is the portion of resources used in furnishing services that reflects the general categories of physician and practitioner practice expenses, such as office rent and personnel wages. The PE component accounts for an average of 45% of the total RVUs for a service and thus has a significant impact on physician reimbursement under the PFS.

This market research report presents recommended commercial prices for the items of equipment and supply that make up the CMS Direct Practice Expense Inputs (DPEI). In addition, it documents the methodology used to develop recommended prices for the equipment and supply components of the DPEI.

2.0 Overview of the Medicare Physician Fee Schedule

The Medicare Physician Fee Schedule was implemented by CMS to reimburse physicians and certain other designated providers for medical services furnished to Medicare beneficiaries under Part B of the Medicare program. The PFS uses a resource based relative value scale to calculate compensation based on a schedule of unique current procedural terminology (CPT) codes, each representing a discrete reimbursable procedure or other service. The RBRVS methodology captures the value of the resources that are used in providing the service relative to the value of all other services reimbursed pursuant to the PFS.

The reimbursement payable for each CPT code is based upon the values of three separate inputs expressed in the form of “relative value units” (RVUs). A RVU is a nonmonetary unit of measure that indicates the relative resources used to provide a given medical service. The RVU system of reimbursement was designed to provide an objective means of comparing the spectrum of covered medical services by weighing the resources consumed in providing a given service relative to all other services reimbursed under the PFS.

In determining the PFS reimbursement for a service, CMS considers three RVU inputs, which collectively account for physician work, malpractice insurance expense, and practice expense. The physician work RVU (wRVU) considers the physician’s expertise, physical effort, and the time and technical skill spent in performing a service. The malpractice RVU (MP RVU) accounts for the cost of professional liability coverage attributable to a service. The practice expense RVU (PE RVU) is comprised of two types of practice expense: direct practice expense and indirect practice expense. The direct practice expense inputs capture the cost of equipment, medical supplies, and clinical and administrative staff that are directly utilized in providing a particular service for a patient. The indirect practice expense component of the PE value accounts for the cost of items and services that are necessary to operate a medical practice but that are not directly consumed in providing a given service. Indirect practice expenses include items such as the cost of rent, office equipment, utilities, and administrative personnel.

This Market Research Report focuses on the direct practice expense inputs, specifically the inputs for medical equipment and medical supplies.

2.1 Direct Practice Expense Inputs

The DPEI includes descriptions and price information for many medical supply and equipment items, each of which is identified by a unique CMS-defined code. Within the DPEI, each PFS service code is linked to one or more supply or equipment items, along with the quantity of supplies or number of equipment minutes typically used by a provider when furnishing a given

service reimbursable under the PFS.

The prices for medical supplies and medical equipment are critical elements in determining the direct costs used in calculating PE RVUs for individual codes. CMS develops PE RVUs by looking at both the 1) direct and 2) indirect physician practice resources involved in furnishing each service. The Direct PE is determined by adding the direct costs of the resources (i.e., costs of clinical staff, medical equipment and medical supplies) typically involved in furnishing a service. The clinical labor cost is the sum of the cost of all the non-physician staff directly involved in providing the service. It is the product of the time devoted by each staff type in providing the service and the wage rate for that staff type. The medical supply cost is the sum of the cost of the supplies generally used in providing the service. It is the product of the quantity of each supply used and the cost of that supply. The medical equipment cost is the sum of the cost of each item of equipment associated with the service. It is the product of the number of minutes each piece of equipment is used in providing the service and the equipment cost per minute.

Calculating the cost of the resources that comprise the practice expense inputs assigned to each CPT code generally relies on information about equipment and supply pricing that is submitted by the public to CMS, as well as on pricing recommendations from various other sources. CMS has routinely accepted public submission of invoices as part of its process for developing payment rates for new, revised, and potentially misvalued codes. In addition to its annual ongoing refinement of RVUs, section 1848(c)(2)(B)(i) of the Act requires that CMS review the value of all RVUs at least every five years.

CMS uses a detailed methodology for translating the equipment and supply resources required to furnish a given service compensable under the PFS into service-specific PE RVUS. For a more detailed explanation of the PE methodology employed by CMS, refer to the CY 2010 PFS final rule with comment period (74 FR 61743). In addition, Appendix A: “Background of Medicare’s RVU Reimbursement System,” describes the RVU system in more detail.

2.2 Physician Expense CY2018 Data

Secondary market research was conducted on prices for 2,072 unique equipment and supply codes, each identified by a unique CMS code. CMS provided a table containing a list of 751 equipment codes and 1,321 supply codes. For each CMS code, the table provided the code’s category, a short description of the associated equipment or supply item, the current price assigned to the code by CMS, and the total expenditure made by CMS for that item in the most recent reported fiscal year.

Table A contains a brief summary of the total 2,072 equipment and supply codes submitted by CMS for this market research study. Appendix A, Table E and Table F, provide a more detailed

summary of the 751 equipment codes and 1,321 Supply codes that were researched.

Table [A]: Equipment and Supply Summary

Equipment Summary	Total		Supply Summary	Total
1. Documentation	46		1. Accessory, Procedure	290
2. Furniture	44		2. Cutters, Closures, Cautery	57
3. Imaging (all)	99		3. Gown, Drape	51
4. Laboratory	104		4. Hypodermic, IV	93
5. Room – Lane	29		5. Imaging Equipment	1
6. Scopes	47		6. Infection Control	26
7. Other Equipment	374		7. Kit, Pack, Tray	117
8. Insufficient Data	8		8. Lab	310
			9. Office Supply, Grocery	92
			10. Pharmacy, NonRx	89
			11. Pharmacy, Rx	96
			12. Wound Care, Dressings	95
			13. Insufficient Data	4
Total Equipment:	751		Total Supplies:	1,321

2.3 Equipment and Supply Descriptions

Individual equipment and supply descriptions contained in the CY2018 DPEI database were used to research the commercial and GSA prices. Many of the descriptions were insufficient to support accurate identification of a specific product, so CMS also supplied supporting invoices for each equipment and supply item, if available, for further clarification. Most of these invoices dated back to 2004 and 2005 and often provided little relevant guidance. Technological advances and market forces have resulted in significant changes to medical equipment and supply items over the last fourteen years. Some items are no longer produced, while others have significantly changed in design, features or operation. Many manufacturers are no longer in business. The problem of identifying the market prices of equivalent products based on invoices from 2004 or 2005 was most acute in regard to equipment codes, since the nature of medical supplies generally allowed the identification of current products, even if the manufacturer and/or product name had changed.

A number of the higher priced CMS codes for equipment and supplies “bundle” a combination of multiple items under a single code. For example, each “Room-Lane” code consists of an established list of equipment items that are used in a specific procedure. The DPEI describes CMS Code EL008 as “Room, MRI,” and the description of the items included under this code includes an MRI machine and a list of additional, discrete items that are bundled under the code. Therefore, the market price for this bundle not only includes the market price of the MRI machine but also the price of all of the individual equipment and supply items that are included in the code description.

A similar trend applies to certain CMS supply codes. Many of the most highly utilized supply codes are the “Kit,” “Pack,” and “Tray” codes. For example, CMS Code SA047, described as “Pack, EM visit,” includes an extensive number of supply items that would be used for an emergency room visit. These bundled codes -- Room-Lane codes for equipment and Kit, Pack, and Tray codes for supplies -- represent a significant proportion of the annual financial outlay that CMS pays pursuant to the PFS.

CMS added most of these bundled codes to the DPEI based on recommendations from the AMA/Specialty Society RVS Update Committee (RUC). The RUC recommended these bundles in order to simplify claims submissions around CPT and HCPCS codes, aligning reimbursement for equipment and supplies to physician practice norms.

3.0 Market Research Sources, Methodologies, and Observations

3.1 Overview

The production of medical equipment and supplies in the United States is dominated by a relatively small number of large, diversified companies. Large medical device and supply manufacturers are usually consistently profitable, with many generating net profit margins well above ten percent annually. Smaller companies occupy a limited space in the market; generally these companies each engage in the development and sale of devices for a specific therapeutic area.

Market dynamics for medical equipment and supplies vary greatly. Markets for common, lower-priced products, such as latex gloves, syringes and other routine items, are price competitive. Companies may offer discounts to secure high volume purchases or repetitive sales. In contrast, the market for technically sophisticated devices and products, especially when they are under patent protection or contain proprietary components, are less competitive and may feature higher, less flexible pricing.

To effectively capture data from the diverse medical equipment and supply market, a phased approach was employed to coordinate market research, as shown by the key activities outlined in the graphic below.

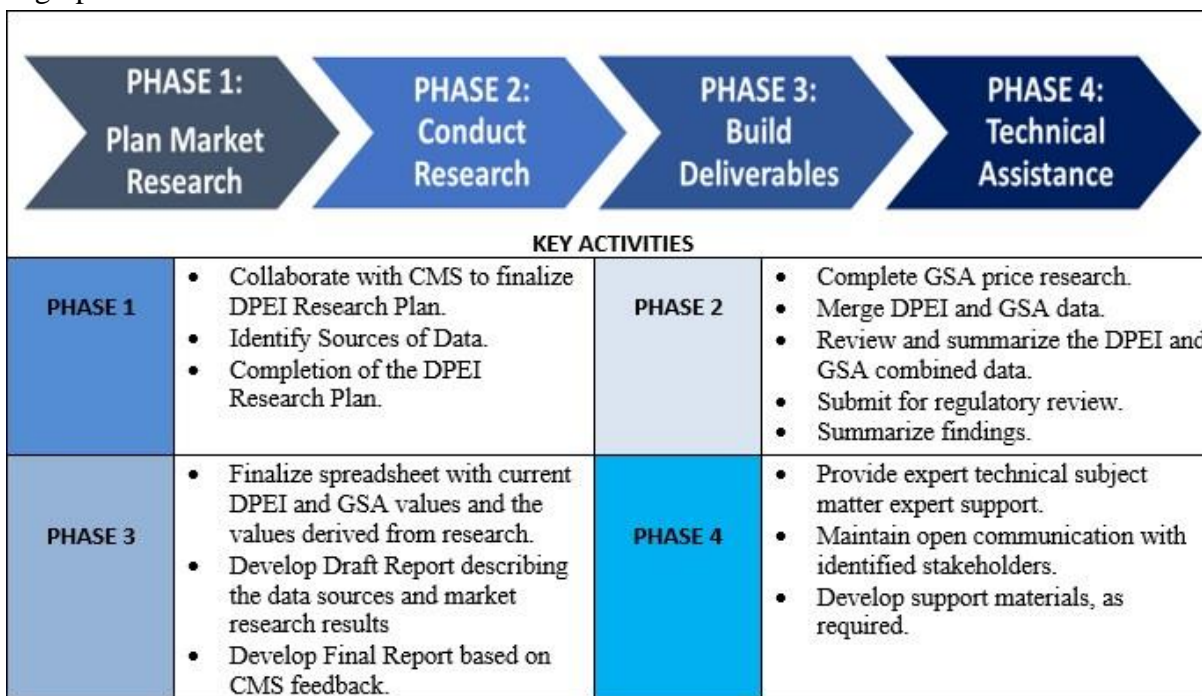


Figure 1: DPEI Market Research Plan Phases

An extensive market research plan was developed to identify recommended updates to prices contained in the DPEI database. See Attachment D: “Market Research Plan,” for a complete description of the full plan.

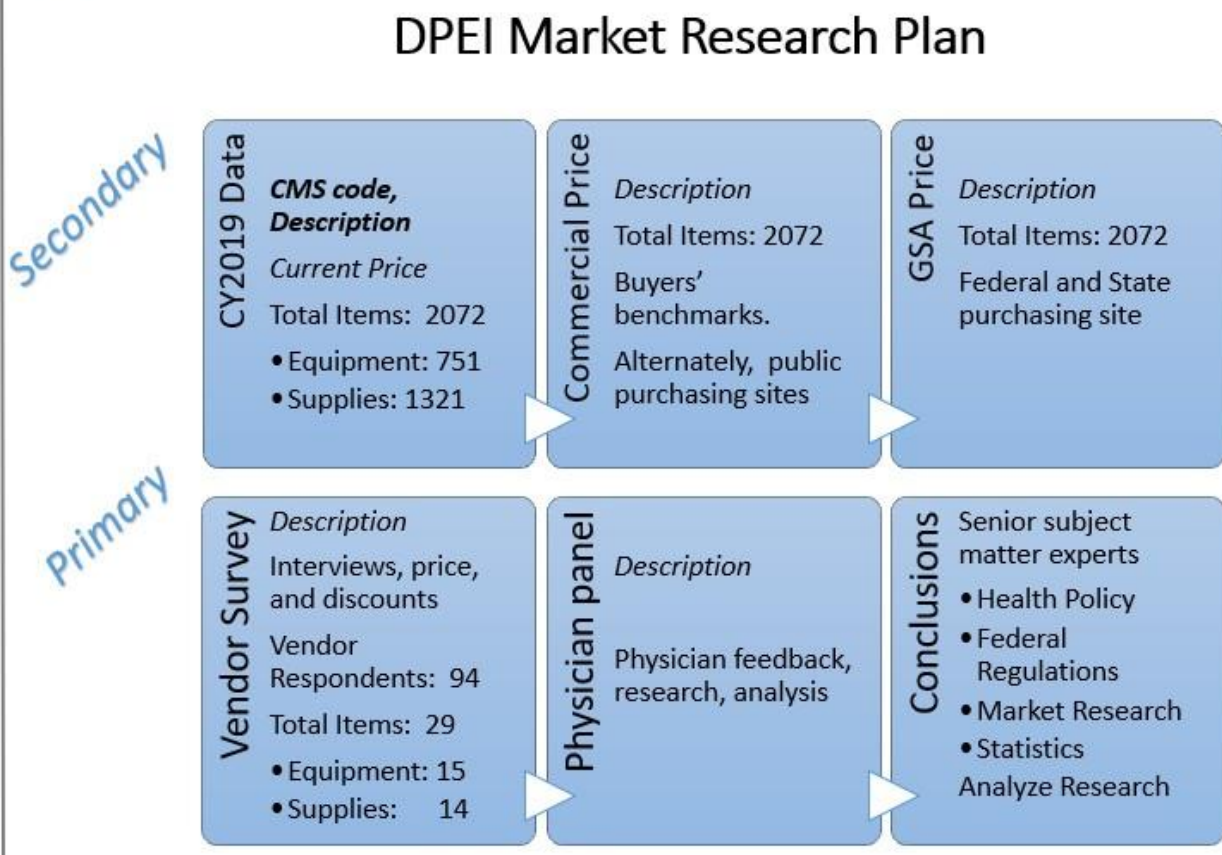


Figure 2 DPEI Market Research Plan

CY2018 DPEI data supplied by CMS formed the foundation of the market research performed. Data included 751 pieces of equipment and 1,321 supply items, as described in Sections 2.2 and 2.3 above. To develop the most representative estimate of prices paid by physicians and other providers, including average discounts, both primary and secondary data sources were employed to gather a robust sample of market prices.

Secondary Research:

Commercial Price: To estimate commercial price, this market research relied on multiple sources of price and market share data, extraction and analysis. The market share means the portion of the market that purchases a particular product. For example, sources included a database that compiles multiple buyer-submitted prices for medical equipment and supply items to create a

benchmark source of typical commercial prices, net discounts. When no buyer benchmark data were available for a particular product, public purchasing sites were used to collect pricing information. A price analysis was performed that included contrast variation between the current CMS prices and the commercially available prices to inform the pricing options for CMS to update the DPEI.

GSA Price: Using GSA Advantage, vendor equipment and supply prices available on the GSA Schedule were researched and analyzed.

Primary Research:

Vendor Survey Market Research: A large global research corporation was retained to conduct an in-depth market research survey regarding medical equipment and supply pricing. This survey was conducted from December 1, 2017 to January 1, 2018 and included 94 medical sales professionals from across the United States with market knowledge of fifteen (15) high-priority DPEI medical equipment and fourteen (14) high-priority DPEI supply items. A screening questionnaire was developed to identify respondents who met prescribed participation requirements. The survey employed a discussion guide with in-depth questions regarding the high-priority medical equipment and supply prices, discounts, and other pricing decisions. Interviews averaged approximately 24 minutes in length to allow for enriched data collection, context, and differential insight. The vendor survey methodology and observations are summarized in Sections 3.3.5, 3.3.6, and 3.3.7, below.

Physician Panel: An expert Physician Panel was assembled to serve as a focus group to provide context, insight and guidance regarding the resources and methodology used in researching medical supply and equipment pricing data. Members of the Physician Panel did not contribute pricing data but instead provided contextual support to the research project. The panel was composed of physicians who had experience over the course of their careers in a spectrum of practice settings: ranging from solo practice, to small group practice, to large multi-specialty group practice, to hospital employment and academic medical practice. Each physician had been in practice for at least ten years, and most had practiced medicine for substantially longer. The members of the Physician Panel represented various specialties, in an effort to provide broad-based context and validation for the market research design and results.

Research Priorities: In order to prioritize the research, CMS organized the equipment and supply codes based on “Total Spend.” The Total Spend for a given CMS code is the product of its DPEI price and the annual utilization of that code, which produces the total annual CMS expenditure for that CMS code. The market research plan priorities for equipment and supplies were prioritized based on the Total Spend, by separating equipment and supply codes into four research priorities based on the amount of Total Spend for each code. Items with higher Total Spend received higher

priority. These four categories include Top, High, Medium, and Low equipment or supply codes and items were categorized based on where they rank for total utilization. While online commercial market research and GSA research was conducted for all equipment and supply codes, the vendor survey market research was conducted only on the Top priority codes, which were the codes with the highest Total Spend. See Tables G and H, “Vendor Survey Equipment Prices,” and Tables K and L, “Vendor Survey Supply Prices,” in the Appendix, for the Top equipment and supply codes prioritized by Total Spend.

CMS provided a total of 751 equipment codes. Based on CMS’ Total Spend, the 751 equipment codes were prioritized as follows:

- 14 Top equipment codes,
- 68 High equipment codes,
- 225 Medium equipment codes,
- 444 Low equipment codes.

CMS provided a total of 1,321 supply codes, which were prioritized based upon CMS’ Total Spend, as follows:

- 26 Top supply codes,
- 118 High supply codes,
- 396 Medium supply codes,
- 781 Low supply codes.

The prioritization of the equipment codes by Total Spend illustrates that the most utilized CMS equipment codes are the Room-Lane codes and other bundled codes. These bundled codes tend to have a high dollar value, and consequently, they represent a significant proportion of the financial outlay for Direct PE RVUs. For these reasons, a significant proportion of the bundled codes were prioritized for additional primary research. In summary, the following market research was performed, described in detail below:

Secondary Research Sources

1. An aggregate health system proprietary database with discounted prices (Buyers);
2. Publicly available vendor resources, e.g. Amazon.com and Cardinal Health; (Vendors); and
3. The General Services Administration Schedule (GSA);

Primary Research Sources

1. A survey of vendors and other suppliers for the Top priority items;
2. Physician Panel to provide context and feedback regarding the market research performed; and

3. Analysis and feedback from a team of senior healthcare policy and regulatory subject matter experts, both internal and external.

3.2 Research Sources

3.2.1 Buyers Benchmark Databases

Commercial prices were gathered from subscription-based benchmark databases for medical supplies and equipment that is operated by a nonprofit organization that represents more than 5,000 members. Its members include integrated health delivery systems, hospitals, physicians and other providers, as well as public and private payers, federal and state agencies, policymakers, and accrediting agencies. The Department of Veterans Affairs, the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA), and the Indian Health Services (IHS) also contract for benchmark data from this organization.

Providers submit contracts and purchase orders that contain negotiated market prices on hundreds of thousands of items of capital technology equipment and millions of unique supply items. These two databases represent billions in spend data from providers nationwide. The supply data is based on actual purchase orders submitted by the organization's member providers. The equipment data is based on negotiated contracts with vendors, typically containing the agreed-upon price. The equipment database includes total quoted dollar amount, total number of quoted units, total number of quotes, and market share.

These equipment and supply databases comprise a comprehensive market research tool that permit users to access information through a database search for all available suppliers, vendors, manufacturers, and products. One of the greatest benefits of these databases is their large sample size and the robust research tools that provide hundreds or even thousands of data points for the prices of each product.

Another strength of this database is the rich depth of information on actual purchasing habits. The equipment and supply databases' dollar amounts, percentages, and item counts are based on data accumulated over a rolling twelve-month period and are updated in real time. The items reported in the databases can be sorted by region, bed size, market share, manufacturer, and volume of purchase orders. In addition, the database permits a user to review what items were grouped together within individual purchase orders, which often facilitates the ability to analyze items that are included in bundled codes. These databases provide not only the list price for every item catalogued, but also the average market price paid, including the typical discounts extended, based on the quotes and purchase orders received. Use of these databases provides access to pricing data compiled from recent purchases across the nation, often comprising thousands of individual

transactions.

3.2.2 Amazon Business

Amazon Business is a division of Amazon.com that provides a purchasing platform for registered businesses to buy supplies and equipment. It advertises “business only” pricing that features quantity discounts and tiered-pricing discounts for high-volume purchases on certain items. A user may request a volume discount on any product from a participating seller by clicking “Request a Quantity Discount.” The website allows purchasers to see multiple offers on a product from a variety of sellers, so that broad comparison of price and terms is transparent and easily available. Other than the possibility of obtaining a price discount based on the quantity of items purchased, there is no identifiable mechanism for negotiating discounts to posted prices. Free expedited shipping is available for many items, and Amazon allows the shipping benefits of an individual “Prime” account to be extended to a business user account.

Amazon Business launched in 2016. It currently offers business pricing and quantity discounts on more than five million products. In the health care arena, Amazon Business features a large array of medical supplies including infusion pumps, catheters, IV bags, sutures, forceps, hospital beds, scalpels and some lab items. The website also features a broad selection of common medical equipment. Medical equipment regulated by the FDA, highly specialized equipment, and equipment that represents a significant capital investment is generally not available. Amazon Business generated \$1 billion in sales in its first year and is expected to rapidly increase its market penetration in the sale of common medical supplies and equipment.

3.2.3 Cardinal Health, Inc.

Cardinal Health, Inc. is a Fortune 500 company that specializes in the distribution of medical supplies and equipment, serving more than 100,000 locations, including more than 75% of hospitals in the United States. Cardinal offers a broad range of medical supply items, pharmaceutical supplies, laboratory supplies, patient monitoring equipment, and durable medical equipment. It also offers a narrow range of some specialty-specific equipment, such as orthopedic surgical products and accessories and cardiovascular devices. In addition to distributing products from a variety of independent manufacturers, Cardinal Health also manufactures certain medical and surgical products under its proprietary brand that are sold through its distribution system.

3.2.4 GSA Schedule and GSA Advantage

GSA contracts with vendors under the GSA Schedule to provide the lowest possible prices to state and federal government purchasing agents. GSA Advantage is the GSA’s online purchasing

service and is promoted as “the Federal Government’s premier online shopping superstore.” It is designed to provide an efficient purchasing portal for federal agencies to acquire various goods and services. GSA Advantage seeks to ensure that the lowest possible price is available to federal purchasers and to reduce the time and cost of obtaining goods and services from qualified contractors. The online portal provides access to millions of commercial products and services provided by contractors who must go through a stringent qualification process to be allowed to sell their goods to the federal government through GSA Advantage.

In order to qualify as a contractor on one of the various GSA schedules, a contractor must develop and submit a proposal to the GSA Administrator. This proposal is essentially an offer to sell products or services to federal and state agencies. The GSA proposal process is thorough, and the negotiation of a potential GSA contract can take up to a year to process. Contractors submitting a proposal must offer the government their most favorable price, and the validity of this price must be backed by evidence of purchase orders and invoices. The GSA Administrator will negotiate most offers and generally seek an additional discount off the contractor’s most favorable price. Since vendors are required to furnish their “best offer” to GSA, the prices reported on the website can be assumed to represent a floor for government pricing.

GSA Advantage allows a product to be identified through a search by category, supplier, or descriptive terms. Detailed product information, including the GSA negotiated price, is available for each item. The GSA website may be searched and viewed by the public; however, only qualified government agencies may initiate a purchase.

GSA Advantage offers a rich data source for research on the prices of medical equipment and supplies. It is a transparent resource that accurately shows available prices for a broad range of items available to federal and state government agencies. The posted price for any item can be trusted as an accurate reflection of the price that would be paid in an actual transaction between the contractor and the federal government. It is never merely an offer or quoted price.

3.2.5 Primary Market Research: Vendor Survey

Primary market research was conducted through interviews of identified representatives of medical equipment and supply vendors, using accepted methods of primary market research. Vendors were selected as primary market research subjects because they are in a position to serve as reliable and available sources of unbiased primary market research data regarding prices for medical equipment and supplies. As a point of contact between product manufacturers and the medical entities that purchase the products, vendors are familiar with industry practices regarding pricing and discounts. They can also be expected to have access to accurate price data across a range of products. Product manufacturers would also possess detailed pricing, discount, and sales information for their products, but attempts to obtain this information from manufacturers through

public resources or through direct contact with manufacturers were unsuccessful because detailed pricing and discount information is proprietary, and the vast majority of manufacturers refused to disclose this type of information. Purchase managers for physician groups and other health care providers were also considered as sources of primary pricing information. Practical difficulties in identifying a representative sample of purchase managers for physician groups who were willing to participate in market research made it impractical to pursue this avenue of primary research. For these reasons, vendors were selected as the group possessing both the most abundant available knowledge and providing a deep sample pool.

The vendor survey gathered data from 94 vendor respondents out of approximately 400 vendors contacted. Of these 94 vendor respondents, 15 vendors exclusively sold medical equipment; 32 vendors exclusively sold medical supplies; and 47 vendors sold both medical equipment and medical supplies. In addition, half of the vendors interviewed had experience selling both medical equipment and supplies, resulting in 62 vendor respondents who possessed experience selling medical equipment and 79 vendor respondents with experience selling medical supplies. Each respondent had to have a minimum of three months experience; however, a full 75% of the respondents had more than three years of experience selling medical equipment, medical supplies or both.

3.2.6 Primary Market Research: Physician Panel

A Physician Panel was assembled to serve as a focus group to provide context, insight and guidance regarding the resources and methodology used in researching medical supply and equipment pricing data. The panel was composed of physicians who had experience over the course of their careers in a variety of practice settings: ranging from solo practitioner, to small group practice, to large multi-specialty group practice, to hospital employment and academic medical practice. Each physician had been in practice for at least ten years, and most had practiced medicine for substantially longer. The members of the Physician Panel represented a limited number of specialties; the Physician Panel was not designed to serve as a statistically significant sample of physicians or to provide market research data to be directly used in establishing product pricing. Rather the Physician Panel was used as a contextual resource and sounding board for the validation of the market research design and results through both group sessions and individual one-on-one conversations. Topics discussed included validation of the research methodology; the physicians' experience with, and understanding of, the RVU reimbursement methodology; background information regarding commercial sources used for the acquisition of practice supplies and equipment; procedures used for purchase of supplies and equipment; and the role of negotiation and discounts in such acquisitions. Each member of the Physician Panel reviewed collected pricing data for selected equipment and supply items to provide feedback and commentary on the prices collected from secondary market research. Each

physician reviewed the pricing data collected for supply or equipment items that he or she was familiar with based on prior practice experience. The opinions and insight acquired from the Physician Panel were used to contextualize primary and secondary research efforts and were not directly utilized to establish recommended pricing.

3.3 Research Methodologies and Observations

3.3.1 Commercial Price Methodology

The goal of the market research undertaken was to identify the actual commercial prices paid by physicians and other providers for the specific equipment and supplies making up the DPEI database. Research indicated that the retail prices for medical equipment and supplies are commonly subject to discounts based on one or more of the following factors: the volume of items purchased, the timing of the purchase, and the inclusion of other items in the purchase. Therefore, the price paid in actual purchases can differ substantially from the quoted price of an item. Because it provides average pricing information, net typical discounts, the Buyer benchmark database was the primary source for collection of commercial price information.

To research the market price for supplies in the Buyer database, the researcher identified the CMS supply description for each specific code, as described above. Using search terms derived from the CMS description, the researcher identified the set of potential products that matched the CMS description for each code. Manufacturer and Vendor catalogs were used to validate medical equipment and supplies and catalog number alignment within the database. Then the researcher narrowed the search results by sorting the actual purchase orders to identify those from relevant purchasers. Next, the researcher identified the three most commonly purchased products that matched the supply description, based on the number of members submitting purchase orders. Finally, the top three products and their prices were recorded in the research database.

To research the equipment market prices, a similar process was employed. The researcher first used the CMS description for each equipment code to develop search terms for use in the Buyer database. Using these search terms, the researcher identified a set of potential products matching the CMS description. Historic invoices provided by CMS were next used to narrow the search results by refining the group of products. The researcher then sorted the price quotes obtained from the Buyer database for the item of equipment (near-final quotes) by reported market share to capture the top three products fitting the item's description. In addition to market prices and samples sizes, the researcher also collected market share data for the top three equipment models purchased, as reported by the Buyer database.

If the Buyer benchmark data was unavailable for a particular item or was difficult to align with a product description and code for other reasons, the researcher would search other secondary

market sources such as Amazon Business and the Cardinal Health Equipment and Supply Catalog to identify individual vendor pricing.

In all instances in which products could be identified on the Buyer benchmark, the Commercial Price reported for each product is the weighted average of the Buyer benchmark data collected. Equipment from the Buyer benchmark database is weighed by market share for the most representative estimate of the market price. In the case of supplies, for which market share estimates were not collected, as well as for data gathered from sources outside the Buyer benchmark, the most representative estimate of market price is the weighted average sample size (n). The term “n” means the numerical quantity of invoices and data points. In addition to the Commercial Price, this report furnishes a GSA-Price and a Recommended Market Price for all items of equipment and supply, so that three alternative pricing methodologies are available for comparison.

3.3.2 Methodology to Determine the Commercial Price for Bundle CMS Codes: Room-Lanes, Kits, Packs, and Trays

Within the set of CMS medical equipment codes used in calculating the DPEI, there are twenty-nine Room-Lane equipment codes. Each includes multiple equipment items that are generally utilized together to provide a specific service or procedure. Determining a Commercial Price for these Room-Lane equipment codes requires calculation of a bundled price that includes the individual prices of a number of items, generally consisting of a main piece of equipment and multiple other equipment items that are used in conjunction with the major piece of equipment to provide a service billable under the PFS. For example, “Room MRI” is a Room-Lane code, and the CMS description of its equipment components is as follows: “MRI machine, power injector, computer work station, MRI software, and monitoring hardware.” The major item of equipment within this Room-Lane code is the MRI equipment, an expensive item of capital equipment. However, market research indicates that the actual invoice price of expensive items of capital equipment, such as MRI machines, may be subject to substantial discounts, especially when purchased in conjunction with other items of supporting equipment and supplies.

For Room-Lane equipment, the proprietary Buyer benchmark data was used to determine the actual commercial price paid, which was often substantially discounted from the invoice or list price quoted by the manufacturer. The purchase orders accessible on the Buyer benchmark database also report the prices of other items of equipment generally purchased as a bundle with the main piece of equipment. This information was valuable in researching Room-Lane codes. Many of the additional components reported in the proprietary Buyer database were found to align with CMS’ Room-Lane equipment descriptions.

To determine the commercial price for Room-Lane items such as the MRI Room code, first the price of the top three MRI models by market share was determined and then the reported prices of

the additional components were added to that market share value. The recommended price of each component was determined by market share and N count. The market share means the portion of the market that purchases a particular product. The prices of all the components of each Room-Lane were then added together to determine the commercial price of each Room-Lane.

Market research to establish the commercial prices of products bundled into the CMS supply codes for “Kits, Packs, and Trays” presented unique challenges. Generally, there are substantially more components included in each Kit, Pack, and Tray code than there are in an equipment Room-Lane code. While market research indicated that many supplies included in Kit, Pack, and Tray codes are sold with components packaged together, establishing the commercial price for other bundled supply codes did require separate market research for the price of each supply item included in the bundled code. For each supply item in the Kit, Pack, and Tray codes, every effort was made to identify three separate price points. These prices were averaged to arrive at an average commercial price for each item contained within the description of the bundled CMS code. The average prices of all included supply items were then summed to arrive at the recommended commercial price for the bundled code.

3.3.3 Commercial Price Observations

A comparison of typical discounts for most of the Top equipment codes was developed by drawing on statements both from Vendors regarding discounts offered and from the Buyers benchmark reports of discounts received. The following table shows that the Buyers benchmark indicates that purchasers of equipment are receiving substantially greater price discounts than Vendors report offering:

Table [B]: Equipment Discount Comparison

CMS Equipment Description	Discounts: Buyers Benchmark	Discounts: Vendor Survey	Difference: Reported Discount
1. Room MRI	51.6%	18.67%	+
2. Room ultrasound vascular	8.03%	17%	–
3. Room CT	51.6%	14%	+
4. IMRT accelerator	67.56	15.67%	+
5. Patient-worn telemetry system	34.06%	12.67%	+
6. Room angiography	45.43%	7.67%	+
7. Room basic radiology	25.90%	14.33%	+
8. Room ultrasound general	48.53%	15%	+

9. Radiation virtual simulation system	48.33%	8.33%	+
10. Radiation treatment vault	N/A	10%	
11. Lane OPH screening	18.53%	9.67%	+
12. Room radiographic-fluoroscopic	51.06%	13%	+
13. Attended sleep diagnostic system	N/A	18.67%	
14. Lane OPH exam	36.43%	8%	+

3.3.4 GSA Price Methodology and Observations

Researchers attempted to match each piece of equipment and each supply item that was encompassed by the CMS codes within the DPEI with a product listed on GSA Advantage. When a matching product was identified in the GSA website, its GSA description and its price were harvested and are included in the research findings attached to this report. When no product could be identified on the GSA website for a given CMS code, this fact was noted by entry of “N/A” in the pricing data spreadsheet.

Use of the GSA website to research supply and equipment pricing was found to have a number of limitations. Only suppliers that meet stringent qualifications and that complete a lengthy and detailed application process are eligible to participate in GSA Advantage. These requirements sharply curtail the number and type of suppliers whose products may be accessed on the GSA Advantage website. Only products that are purchased by federal agencies or other qualified government entities are listed on the GSA Advantage website, which has the effect of eliminating a number of medical supplies and equipment that are covered by CMS DPEI codes. This limitation was especially acute when researching bundled codes for equipment rooms and lanes, or supply packs, kits, or trays. The GSA website does not record comparable bundled purchasing of medical equipment or supplies, so no GSA pricing could be recovered for products included in the bundled codes organized as rooms, lanes, packs, kits or trays. Finally, the prices listed on the GSA Advantage website are required to be the supplier’s best offer, and thus may often be lower than prices that are available to non-governmental purchasers.

While the GSA Prices are designed to be the lowest available, the lack of data on GSA for many equipment codes may have impacted the results. The lack of data readily available on GSA may indicate that government providers typically use other contract vehicles to purchase discounted medical equipment. It may also reflect vendor reluctance to offer deeply discounted prices for medical equipment on-line.

3.3.5 Vendor Survey Methodology

The goal of the primary research was to identify a range of typical discounts and representative prices for various supplies and equipment in the current market and to understand how discounts and other factors influence pricing decisions. CMS total annual spending for each CMS code was the primary selection criteria for choosing which CMS codes would be the subject of primary market research. The survey was conducted in a manner that vendors could respond anonymously to facilitate vendors responding freely and without bias. To ensure thorough survey interviews regarding the products constituting each selected CMS code, the number of CMS codes subject to primary market research was limited.

The Top 14 medical equipment codes and 14 of the Top medical supply codes based on Total Spend were selected for primary market research. For medical equipment, vendor respondents were queried about their familiarity with pricing and sales of products in a general category of medical equipment and then for each item of equipment, they were provided the top three models by market share as examples. For example, the interviewer would ask, “Are you familiar with the market for MRI equipment? If the interviewee responded affirmatively, the interviewer would ask about specific products related to the general category. Continuing with the above example, the interviewer might ask as a follow-up questions, “Are you familiar with individual models of MRI equipment, such as Siemens’ Magnetom Aera, Magnetom Skyra, or GE’s SIGNA Artist 1.5T?” For medical supplies, vendors were asked to respond to supply descriptions instead of specific examples of products. For example, the interviewer might ask the vendor, “Do you have personal knowledge of the pricing of balloon catheters used for low profile percutaneous transluminal angioplasty of lesions in peripheral arteries?”

The primary market research was designed to focus on several critical issues. As an initial matter, it sought to compare the list prices and typical discounts reported by interview subjects with findings from secondary market research on the market prices of equipment and supply items. Based on the list prices obtained, researchers sought to determine whether the size and type of purchase discounts on medical equipment and supplies varies based on the size of the physician purchasing group and other factors. By conducting the research in this manner, efforts were made to determine the typical list prices and types of discounts that vendors would offer large, medium, and small physician purchasing groups based on the number of providers for specific medical equipment and supply items. One question was whether vendors typically offered large physician purchasing groups better pricing through the use of discounts. The survey instrument contained questions across categories of equipment and supplies to determine what kind of pricing advantage large physician groups enjoyed compared to small physician groups.

In addition, the primary market research sought to gather independent pricing data from vendors on certain items of Top medical equipment and Top supplies so that this data could be compared

to the pricing information for the Top medical equipment and Top supplies gathered through secondary market research efforts. Since many of the Top medical equipment and Top supply codes are bundled codes and thus include a number of individual items bundled together, the primary market research team focused on the most significant piece of equipment and items that would typically be bundles with the purchase of a primary item of equipment or supply.

The first step in selecting respondents for the primary market research was to determine the category of respondents who could provide the most valuable data regarding prices at which medical equipment and supplies are purchased. Vendors were ultimately determined to be the most practical source for obtaining objective opinions regarding the prices paid for medical equipment and supplies. Next, a discussion template was developed according to standard market research principles to guide the interview process. The primary market research team targeted specific vendors who worked for companies that had a minimum of 10 employees for distributors and 20 employees for manufacturers of medical equipment and supplies. The research team identified vendors based on their job title on the D&B/Hoover database by SIC code for medical equipment distributors and manufacturers and by Zoominfo listings of people with sales-related titles at medical equipment distributors and manufacturers.

Once a list of potential interviewees was compiled, the primary market research team began contacting individuals on the vendor list. The team eventually placed telephone calls to approximately 400 potential research subjects and ultimately contacted between 20 and 40 vendors for every completed respondent interview obtained. The criteria for interview subjects were adopted to select only respondents with adequate market knowledge. A vendor speaking on behalf of a company was required to have at least three months of requisite experience in the sale of medical equipment and supplies and to consider himself/herself at least “somewhat knowledgeable” about specific equipment and/or supplies that were the subject of primary research. If the identified vendor did not meet the all of the requirements for participation in the market survey, the primary market research team requested that vendor’s help in locating another person within the same organization who had the requisite experience and who would be willing to participate in the survey. As an incentive to participate, those who successfully completed the respondent interview were paid \$50.00 as compensation for their participation. All data gathered during the primary market research process was compiled for analysis, unless a data outlier was determined by the interviewer to be blatantly incorrect and no further verification of the data could be provided by the respondent.

The 30-day vendor survey plan not only included specific questions about medical equipment and supplies but also the qualifying questions described above. Primary market researchers interviewed more than 90 qualified respondents. Many interviewees were familiar with the medical equipment and supply market, but fewer than half of the initial respondents met the requisite qualifications to complete the interview process. Therefore, sample sizes for individual

equipment and supply items were small, as had been expected. There are a number of interesting observations within the “Vendor Survey Medical Equipment and Medical Supply Observations” sections that follow. These insights are qualitative results, which are anecdotal by design, as is true for most interview surveys. A larger market research study, with an increasing reliance on web and other survey methodologies, would be needed to answer any key questions with statistically certainty.

3.3.6 Vendor Survey Medical Equipment Observations

Selling medical equipment is a specialized profession in which sales representatives focus narrowly on specific equipment. Since most of the Top equipment items fall into the Room-Lane category, the survey addressed the prices and discounts associated with the major piece of equipment in each Room-Lane equipment code examined.

Comparing the commercial prices found through secondary market research to the primary market research equipment data reveals some interesting trends for the Top equipment items. For each equipment code, the commercial price considers any pricing discounts and includes prices for all of the items typically found in the Room-Lane. The vendor survey price is the average list price for the main piece of equipment found in any given Room-Lane equipment code and does not reflect discounts. The average list price was determined by averaging the prices between large, medium, and small purchasers. In addition, Figure 6 and Figure 7, below, show the various items vendors identified that would be typically purchased with the main equipment item. This is significantly different than the current CMS price set forth in Attachment A.

The substantial discrepancy between pricing information gathered from the buyer database and that gathered from vendor surveys highlights the difficulty of comparing prices about these bundled CMS Codes in the medical community. In addition, the vendor survey sample size for any given piece of equipment is small. Therefore, data obtained from the vendor surveys was not used in arriving at the reported Commercial Prices or Price Options.

Table [C]: Equipment Commercial Price Comparison

CMS Equipment Code	CMS Code	Commercial Price: Buyers Benchmark	Commercial Price: Vendor Survey
1. Room MRI	EL008	\$ 1,559,013.50	\$294,633.33
2. Room ultrasound vascular	EL016	\$199,449.31	\$22,333.33
3. Room CT	EL007	\$1,429,967.51	\$155,666.67

CMS Equipment Code	CMS Code	Commercial Price: Buyers Benchmark	Commercial Price: Vendor Survey
4. IMRT accelerator	ER089	\$3,000,966.47	\$7,500
5. Patient-worn telemetry system	EQ340	\$18,565.72	\$48,333.33
6. Room angiography	EL011	\$1,193,425.211	\$143,333.33
7. Room basic radiology	EL012	\$246,216.37	\$105,466.67
8. Room ultrasound general	EL015	\$130,252.57	\$117,300.00
9. Radiation virtual simulation system	ER057	\$601,624.88	\$26,500.00
10. Radiation treatment vault	ER056	\$773,104	N/A*
11. Lane OPH screening	EL006	\$43,678.20	\$28,100.00
12. Room radiographic-fluoroscopic	EL014	\$678,171.26	\$271,666.67
13. Attended sleep diagnostic system	EQ272	\$46,799	N/A*
14. Lane OPH exam	EL005	\$43,884.68	\$35,933.33

*The list price for radiation treatment vault and attended sleep diagnostic system was unavailable as the vendor respondents were unable to provide list prices for these two equipment items.

The Vendor Survey indicated that the list price for each piece of medical equipment varied only slightly depending on the purchaser's size. Tables G and H: "Vendor Survey Equipment Prices", in the Appendix, indicate that while the highest offered seemed to be consistent among all purchasers, the lowest offered price tends to benefit Small purchasers. A wide range of discounts was found to be available, including volume discounts, purchase timing discounts, business size discounts, and other discounts. Vendors were asked whether they provide these types of discounts for each item of the Top equipment. The data showed in the vast majority of cases, some sort of discount was available.

Service Agreement Discounts: The most surprising type of discount was the occurrence of service discounts, which had an effect on many equipment transactions. Vendor surveys indicated that the more expensive equipment items tend to have a service plan available to maintain the

equipment for a specific length of time. Purchase of a service agreement in conjunction with the purchase of equipment has mixed effects, lowering equipment prices in some cases but raising the overall purchase price in others. It is likely that the list price was exceeded despite the service agreement discount because these equipment items are both expensive and quite costly to maintain.

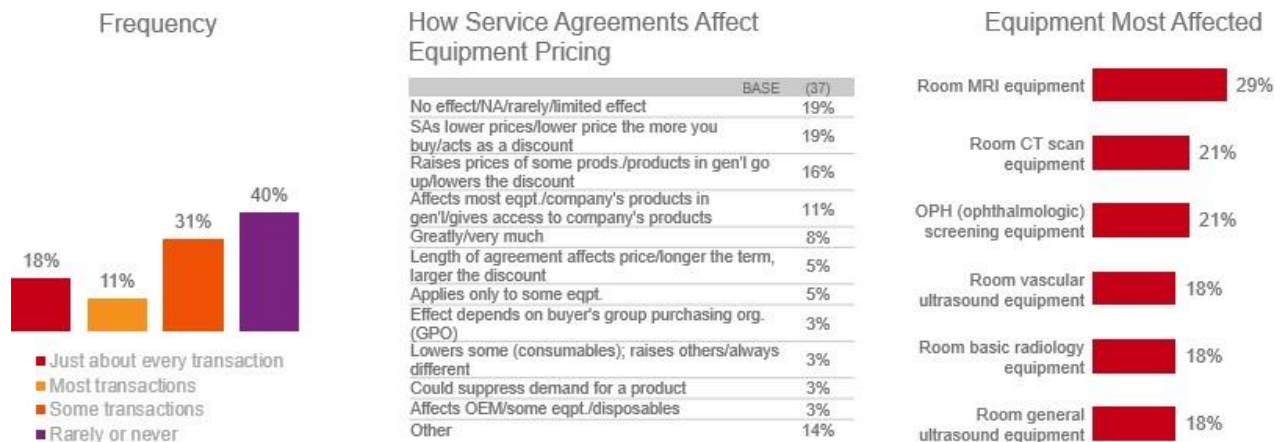


Figure 3: Equipment Service Agreement Discounts

Volume Discounts: In general, vendors reported that volume discounts were available on most equipment items. The largest category of volume discounts was found to be available for radiographic-fluoroscopic equipment and the category with the fewest volume discounts available was ophthalmologist exam equipment. Volume discounts would appear to be most beneficial to Large purchasers, since the price of each individual item purchased is significantly lowered as the total quantity of equipment items purchased increased. Vendor respondents noted that group purchasing organizations tend to have the greatest purchasing power and may receive greater volume discounts due to more equipment items purchased in each transaction.



Figure 4: Equipment Volume Discounts

Timing Discounts: Timing discounts were available about 44% of the time to meet vendor quotas that occurred at the end of the month, quarter, or end of the fiscal or calendar year. These timing discounts were generally applied for purchases that occurred at the end of the month; end of the quarter; end of the fiscal year; or the end of the calendar year. The category where vendors tend to offer timing discounts the most often was radiation treatment vaults with every vendor offering a discount. In general, the equipment offered the greatest discount percent based on purchase time was ultrasound equipment.



Figure 5: Equipment Purchase Timing Discounts

Bundled Purchase Discounts: In general, the discounts offered by vendors to larger purchasers of medical equipment may be better on average. These bundled items were generally purchased with the main piece of surveyed equipment to be used in operating that equipment. Tables I and J: Vendor Survey Equipment Discounts, in the Appendix, show a comparison for the lowest, highest, and average discount available to purchasers for equipment. These discounts consider the multiple types of discounts generally available to purchasers, regardless of size, including volume discounts, purchase time discounts, service agreement discounts, and other various discounts.

Room MRI				Room vascular ultrasound			Room CT scan			IMRT accelerator		
Pillars Maintenance & calibration eqpt. Injectors Sound systems Piccolo chemistry analyzer Film or contrast media Monitor Anesthesia machine Cleaning wax				Gel foam and probe Roll stand Pressure cuffs Extended warranty Doppler Stretcher tables I-stat machine Printer software			Power conditioners Arm, cables, peripheral eqpt. Injectors			Oncology information system software		
Range of discount ¹ Average discount				Range of discount ¹ Average discount			Range of discount ¹ Average discount			Range of discount ¹ Average discount		
Large Mid Small >30% to 40% – >30% to 40% – >30% to 40% – >3% to 5% >3% to 5% >3% to 5%				Large Mid Small >10% to 50% – >30% to 40% – >40% to 50% – >10% to 15% >5% to 10% >5% to 10%			Large Mid Small >20% to 25% – >10% to 15% – >5% to 10% – >5% to 10% >5% to 10% >5% to 10%			Large Mid Small >40% to 50% – >40% to 50% – >40% to 50% – >20% to 25% >15% to 20% >15% to 20%		
19.3 16.3 15.3				23.8 16.6 18.1			12.5 10.0 7.5			33.8 31.3 31.3		
Patient-worn telemetry system				Single-dual head gamma camera system			Room angiography			Room basic radiology		
No mentions				Gating Cardiac and remote viewing stations Biomedical training Warranty coverage			Disposables and/or CT scanner			Exam stools Cabinetry		
Range of discount ¹ Average discount				Range of discount ¹ Average discount			Range of discount ¹ Average discount			Range of discount ¹ Average discount		
Large Mid Small >25% to 30% – >25% to 30% – >5% to 10% – >5% to 10% >5% to 10% >20% to 25%				Large Mid Small >20% to 25% – >30% to 40% – >25% to 30% – >5% to 10% >5% to 10% >5% to 10%			Large Mid Small >20% to 25% – >20% to 25% – >20% to 25% – >20% to 25% >15% to 20% >15% to 20%			Large Mid Small >20% to 25% – >10% to 15% – >10% to 15% – >10% to 15% >5% to 10% >3% to 5%		
19.2 19.2 12.5				14.2 21.7 19.2			22.5 20.0 20.0			17.5 10.0 7.0		

Figure 6: Bundled Equipment Discounts

Because most of the equipment items subjected to the primary market research survey fell into the Room-Lane category, it was important to determine the equipment items that purchasers tended to bundle with a specific equipment purchase. Respondent vendors were asked an open-ended question to determine what additional items a purchaser might typically bundle into their purchase. The results were compiled, and vendors were asked what typical discounts would be applied to a bundled equipment purchase. Many of the major additional components that appear in the Room-Lane categories appeared in these bundles such as injectors, monitoring equipment, and software. Discounts for components sold with equipment range from 7% to 34% on average with Large purchasers often, but not always, receiving a greater discount. This additional discount may be due to their ability to demand a volume discount when purchasing several equipment bundles.

Room general ultrasound				Radiation simulation systems			Radiation treatment vaults			OPH screening		
Additional probes Transducers Picture archives communication station (PACS) Ultrasound jelly Dopplers Ergonomic chairs and tables Aqua sonic gel Service contract Cleaning disinfectant				No mentions			No mentions			Peripheral and calibration eqpt. Hearing eqpt.		
Range of discount ¹ Average discount				Range of discount ¹ Average discount			Range of discount ¹ Average discount			Range of discount ¹ Average discount		
Large Mid Small >30% to 40% – >30% to 40% – >30% to 40% – >3% to 5% >3% to 5% >1% to 3%				Large Mid Small >20% to 25% – >20% to 25% – >20% to 25% – >20% to 25% >20% to 25% >20% to 25%			Large Mid Small >20% to 25% – >20% to 25% – >20% to 25% – >20% to 25% >20% to 25% >20% to 25%			Large Mid Small >20% to 25% – >20% to 25% – >20% to 25% – >3% to 5% >3% to 5% >1% to 3%		
17.9 15.9 13.9				22.5 22.5 22.5			22.5 22.5 22.5			16.3 13.0 10.7		
Room radiographic-fluoroscopic				Attended sleep diagnostic systems			Ophthalmologic exam					
Cables Software packages				Sleep probes Cable Wires Sheets Disposable bedding			Disposable supplies					
Range of discount ¹ Average discount				Range of discount ¹ Average discount			Range of discount ¹ Average discount					
Large Mid Small >30% to 40% – >25% to 30% – >20% to 25% – >20% to 25% >15% to 20% >15% to 20%				Large Mid Small >20% to 25% – >20% to 25% – >20% to 25% – >20% to 25% >20% to 25% >20% to 25%			Large Mid Small >20% to 25% – >20% to 25% – >20% to 25% – >5% to 10% >5% to 10% >5% to 10%					
26.7 22.5 20.8				22.5 22.5 22.5			12.5 14.2 15.8					

Figure 7: Equipment Bundled Discounts

Survey respondents were asked to describe other factors that impacted their company's pricing decisions. Figure 8 illustrates other factors that vendor respondents believed would impact their company's pricing decisions. Some of these other factors include sales to group purchasing organizations, various incentives periodically available to purchasers from manufacturers, and the competitive nature of the medical equipment sales industry.

A lot of our products are sold on group purchasing contracts and timing does not affect that.	Manufacturing incentives.
Before year end, such as fiscal year end prices are better	Market demand
Competitive landscape	Our group may offer promotions to drop price.
Competitive market place. Our pricing gets driven down as the market becomes more competitive.	Our pricing is mostly affected by the standards in the industry for what we are selling. Larger practices are most affected.
Competition & reimbursements also expiration dates & change of representatives also companies changing hands or discontinuing the products	Promotions from manufacture, timing of what the manufacture wants or is promoting.
Consolidation, all hospital merge together, pricing and discounts differ.	Sale rep repore (sic)
Contract renewal.	Seasonal
Customer history	The competitors pricing. The cost to manufacture. The cost of materials. Adoption in the marketplace. Market shares.
Federal tax reform that's going to be a big hit. For all organizations	The discounts can be greater if the co is trying to reach a revenue goal.
Fiscal year timing for equipment purchases. In general, things that affect manuf costs, as in any industry.	The more generic a product, the less timing affects it. Purchase and competitor history, size, GPO awards. Size of institution. If there are new products in the market: we might offer a lower price.
GPO (group purchasing organization) contracts and idm contracts	The profits. We like to have a profit margin of 60 - 70 %
GPO determines prices. It's how they pay us : credit card costs, distributor money, ACH is better.	When a new product comes out in a space. Lower price to maintain market share.
If it is an institution they have influence over the community. They are one of the buyers and they are looked up to by other hospitals, so they have a broad influence.	Year end quarter end. If we are trying to push and hit numbers. GPO contracting. Business review.
Just the end of the quarter	Yes, local vendor contracts/GPO tier pricing/vendor quarterly promotions
Long term contract payment history.	

Figure 8: Other Factors Impacting Pricing

3.3.7 Vendor Survey Medical Supplies Observations

Medical supply sales appear to be a specialized profession, similar to the equipment sales industry. Many sales representatives focus narrowly on specific supplies. Unlike the Top equipment items, which often were sold in bundles that aligned with items contained in Room-Lane categories, sales of most of the Top supply items did not fall into bundles that corresponded with the Kits, Packs, Trays categories. Our primary market research for supply items revealed that typical sales methodologies for medical supplies fell into the Kits, Packs, Trays category bundles for only two CMS codes.

Comparing the commercial prices identified through secondary market research to the primary market research data on supplies illustrates a number of trends for the Top supply items. The secondary market research commercial price data for a given CMS code considers the discounted price and includes all of the items typically found in that CMS code. On the other hand, the primary market research price is the average list price for different quantities of that supply item and is based on very small sample sizes. In addition, the primary market research price does not include discounts and is the average list price regardless of purchaser size.

Table [D]: Supply Commercial Price Comparison

CMS Supply Code	CMS Code	Commercial Price: Buyers Benchmark	Commercial Price: Vendor Survey
1. Flexible stent-graft	SD254	\$2,573	\$1,163.33
2. Balloon catheter for low-profile PTA	SD151	\$332.11	\$222.67
3. 6-0 vicryl suture	SF040	\$4.31	\$21.52
4. LMX 4% topical anesthetic	SH092	\$3.01	\$27.31
5. Embolic protection devices	SD256	\$1,142.89	\$1,141.50
6. Balloon catheter for PTA	SD152	\$189.86	\$301.47
7. 6-inch wide therabands	SJ056	\$0.60	\$17.73
8. Gelfoam dressing 12-7 mm.	SG033	\$9.04	\$15.52
9. Mite antigen	SH006	\$4.48	\$100
10. UltraView universal DAB detection kit	SL488	\$10.08	\$150
11. Staff gown impervious to liquids	SB027	\$4.20	\$5.67
12. Sterile gloves	SB024	\$0.63	\$0.70
13. 1-inch elastic, water-repellent tape	SG075	\$2.06	\$12.40
14. UroVysion molecular test kit	SA105	\$253.26	\$400

One of the primary market research team's objectives was to determine the typical price a Large, Medium, and Small purchaser would pay for specific medical supplies. Similar to medical equipment, the data showed that the list price for each medical supply item varied only slightly depending on the purchaser's size. Tables K and L: Vendor Survey Supply Prices, in the Appendix, show the vendor respondents' reported average price per supply item. With the exception of a few items, reported prices do not vary based on the size of purchaser. Respondent vendors were asked the lowest and highest list price offered to Large, Medium, and Small sized purchasers. The average list price offered to purchasers was then calculated based on the lowest and highest prices. Pricing variances related to purchaser size appeared far more prevalent in the

final amount large purchasers paid for medical equipment after incorporating the various discounts. This was potentially due to volume discounts, since Large purchasers would be likely to buy supplies in significantly larger quantities than medium or small purchasers. For the more expensive supply items, there was little difference in cost regardless of purchaser size. Even for less expensive items, prices differed only slightly.

A wide range of discounts was available for the purchase of supply items, including volume discounts, timing discounts, business size discounts, and other discounts. Vendors were asked whether they provide these types of discounts for each of the Top supplies. Tables M and N: Vendor Survey Supply Discounts, in the Appendix, shows a comparison for the lowest, highest, and average discount available to purchasers for supplies. The data shows that in the vast majority of sales, some sort of discount is applied. It is interesting to note that service agreements impacted supplies as well as equipment. This may be because some of these supplies are included in equipment packages or an indefinite supply agreement existed to continuously provide supplies as needed. The services agreements have the effect of lowering supply prices.



Figure 9: Supply Service Agreement Discounts

Volume Discounts: In general, volume discounts were provided on most supply items, with the largest category of volume discounts available for sterile gloves and the smallest category of volume discounts available for mite antigen. Volume discounts may be most beneficial to Large purchasers since the price of each individual item is significantly lowered as the quantity of supply items purchased increases. Vendor respondents noted that group purchasing organizations tend to have the greatest purchasing power and consequently enjoy the greatest access to volume discounts. In addition, respondent vendors noted that many purchasers buy mass quantities of supplies that would tend to last many months or even an entire year, thus receiving a large volume discount.



Figure 10: Supply Volume Discounts

Timing Discounts: Timing discounts were generally unavailable for supplies, and the time of the year that a transaction was made had little reported effect on the price. If a timing discount, was available, it was generally applied for purchases that occurred at the end of the month, end of the quarter, end of the fiscal year, or the end of the calendar year.

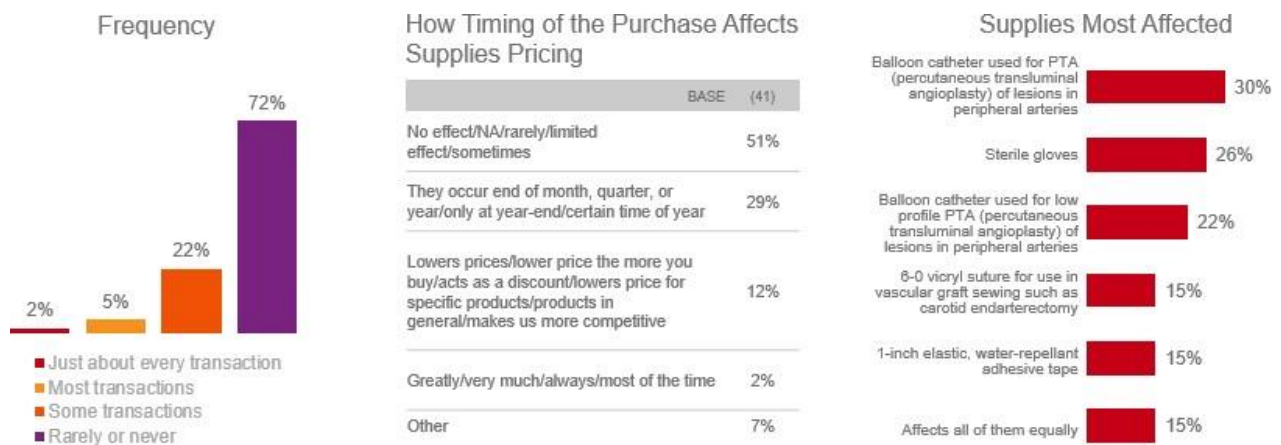


Figure 11: Supply Purchase Timing Discounts

Purchaser Size Discounts: On average, the discounts offered to Large purchasers were significant. The Large purchasers typically obtained better prices on medical supplies due to the discounts, despite the list price being quite similar regardless of the purchaser's size. It is likely the Large purchasers see more significant discounts due to the volume discounts available.

3.3.8 Physician Panel Methodology and Observations

Physician Panel resources were utilized both in virtual group meetings and during individual one-on-one interviews. The physician experts were used as one source of validation for the primary research methodology; as a method of gaining information regarding the commercial sources relied upon by physician practices in obtaining supplies and equipment; and as a source for understanding the role and prevalence of price negotiation and discounts in such acquisitions. At the conclusion of the secondary research process, the Physician Panel reviewed pricing data that was collected for selected equipment and supply items, and Panel members were asked to provide input on items that they reported being familiar with in their practice. The opinions and insight acquired from the Physician Panel were used to contextualize primary and secondary research efforts, but in no case did it directly establish or influence the establishment of recommended pricing.

At the conclusion of the market research process, members of the Physician Panel were furnished with a summary statement of the prices identified. The physicians reviewed spreadsheets of all the CMS equipment and supply codes that had been researched, along with each code's CMS description; the products identified as matching those codes; the GSA and commercial prices collected; and the average market price for each code. Based on their personal experience and knowledge in purchasing equipment and supplies, the physicians were asked to select approximately twenty equipment codes and twenty supply codes representing items that they had personal experience in purchasing. For each code selected, the physicians were asked to give an opinion as to whether the average market price calculated was accurate.

The members of the Physician Panel collectively reviewed 59 equipment codes and 123 supply codes. Based on their personal experience and knowledge of market prices, net discounts, on the set of equipment items they reviewed, the panel members judged that 63% of the average prices calculated for equipment were within the range of their pricing experience; 32% of the prices were higher than their experience; and 5% of the prices were priced below their experience. For supply items, the Physician Panel reviewed 123 codes and reported that 86% of the average prices calculated were within the range of their pricing experience, with 7% of the prices were priced higher than their experience and 7% of the prices were priced lower than their experience.

4.0 Market Research Conclusions

Senior subject matter experts, including experts in the healthcare regulatory environment, health care policy, market research, and statistical analysis, integrated the market research and developed a series of conclusions based on the data collected.

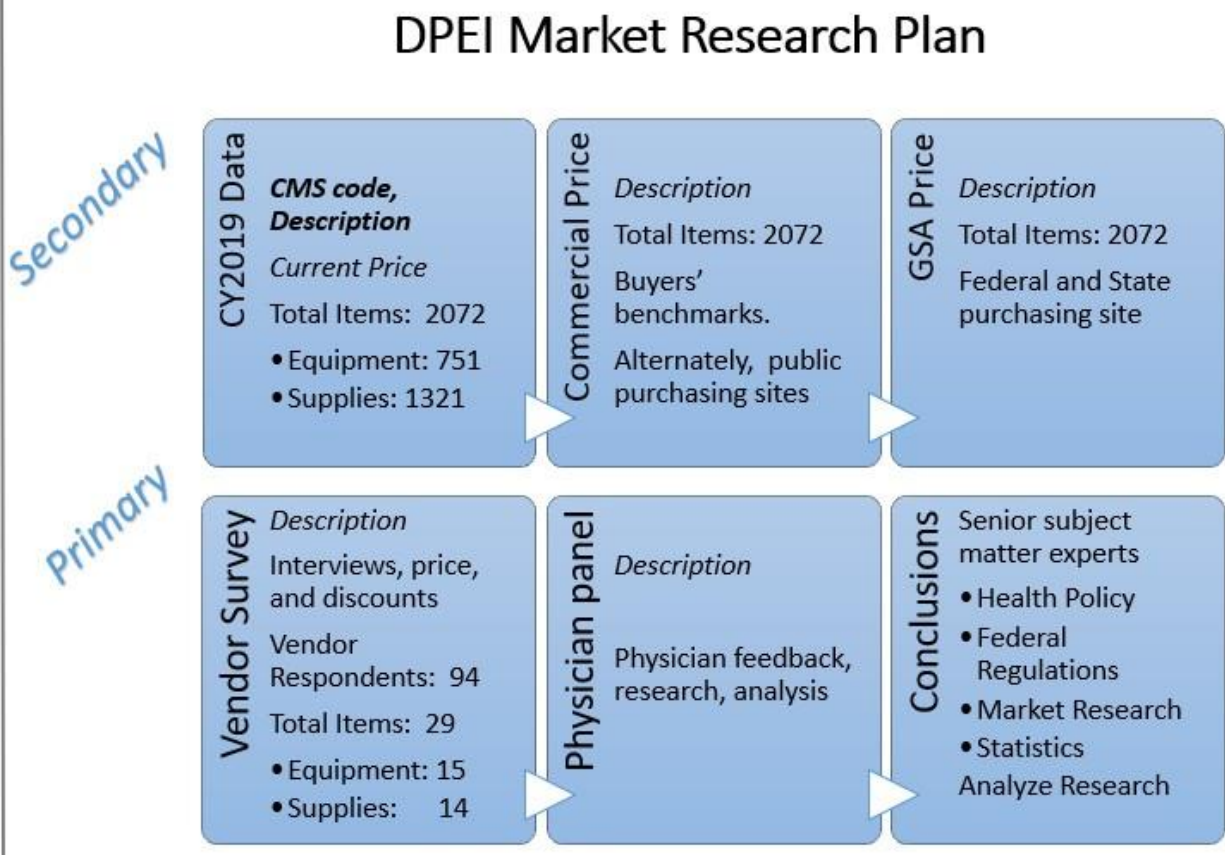


Figure 12: DPEI Market Research Plan

4.1 Equipment: Commercial Price

The Buyer's benchmark database allowed for a robust analysis for each piece of medical equipment researched. The top market share and discounted price points for each item were extracted, resulting in large sample sizes for analysis for each piece of equipment from the database. Market share data and larger sample sizes ultimately allowed for a precise estimation of Commercial Price.

The market research did not reveal any statistically significant difference between the average Current CMS Price and the market research-based Commercial Price. For each CMS DPEI Code, the Commercial Price for equipment derived from the Benchmark database for the top three commercial products represents an average of 68.4% market share with total sample size of 79,933. This commercial price estimate, the weighted average by market share, is a robust and precise estimate of prices that occur in the commercial market. This price was reported as the “Commercial Price,” when sufficient data existed to allow it to be calculated. When insufficient data was available from the Buyer benchmark, the reported commercial price is the simple average of all prices collected from supplier sites like Amazon and Cardinal Health. When available, the weighted average by market share for the Commercial Price was reported. Alternately, when data was unavailable from the Buyer’s benchmark database, up to three individual price points were collected from an alternate public purchasing site. The average of this data was then reported as the Commercial Price.

4.2 Supply: Commercial Price

The Buyer’s benchmark database for supplies provided the most robust price points for each medical supply item. Like the equipment benchmark’s large sample sizes of discounted price points, the Buyer’s benchmark also provides typical discounts for each supply item. The market share for products was not available so the Commercial Price for supplies is reported as the weighted average by sample size. When buyer data for a supply was unavailable, up to three individual price points were collected from a public purchasing site, and the average of this data as the Commercial Price.

4.3 Provider Discounts

Market research from the Vendor Survey indicated that purchaser size does not affect discounts from most suppliers: less than 50% of vendors surveyed reported that greater purchaser size drives greater discounts for supplies. In fact, the research indicates that in some cases vendors actually provide greater discounts to smaller providers based on other factors, including more personal relationships with the providers or attempts to work within smaller supply budgets.

However, service agreements and end-of-quarter purchasing discounts appear to correlate with deeper and more frequent discounts. In addition, smaller providers that are not part of larger health systems can attempt to find similar, if not greater discounts, through:

- 1) Purchasing service agreements,
- 2) Joining a group purchasing organization, or
- 3) Timing equipment and supply purchases.

Research also indicates that the smallest physician practice can increase its purchasing leverage if it strategically makes its purchases toward the end the sale quota cycle.

The research did not indicate any statistically significant difference between the Commercial Price estimates and the current CMS price. In some cases, the Commercial Price estimates are greater than the Current CMS prices, which could indicate expected inflation for some equipment. However, in some instances, the Commercial Price estimates are much less than the current CMS prices. While not a significant trend, there are any number of reasons why the market research Commercial Price estimates were much lower than the Current CMS prices for some items of equipment. Contributing factors could include: a) the data collected represents prices net discounts, while the CMS prices may reflect retail prices; b) actual prices may have decreased due to the lower cost of technology or other changes in manufacturing or demand over the last decade; and c) a few of the lower price estimates might be driven by the complexity of the bundled equipment codes.

Comparison of Current CMS Price with Commercial Price:

Although the averages and totals are similar, many of the Commercial Prices found were greater than the Current CMS prices, which could indicate anticipated inflation. While medical equipment technology has advanced for much of the equipment in the DPEI, commercial prices appear to be stable. This stability may reflect trends often found in the prices for non-medical technology: As first-generation technology evolves, prices for existing and new equipment have remained unchanged or actually decreased over the last decade. For examples, desktop computers (PCs) have become far less expensive over the past decade. For many people, laptops and tablets have replaced desktop PCs and today's laptops and tablets are less expensive compared to the price of desktop PCs of a decade ago.

4.4 GSA Prices

Unlike the Commercial Price, the research did indicate a statistically significant difference between the 'averages' of the Current CMS Price and the 'averages' of the market-researched GSA Price. In contrast to the Commercial Price, the 'average' GSA equipment price was found to be significantly less than the current CMS price.

Comparison of Current Price with GSA Price:

Many of the higher-priced DPEI equipment items were not found on the GSA. In fact, GSA prices were retrieved for only about 400 out of 721 equipment items. There are several reasons GSA Prices are significantly lower than reported CMS DPEI prices. First, GSA Prices are by definition intended to be the lowest available. Also, the fact that many higher-priced items of medical equipment were not listed on GSA Advantage may also have impacted results. The lack of data readily available on GSA may indicate that providers typically use other contract vehicles

for purchasing discounted medical equipment. It may also indicate vendor reluctance to publicize deeply discounted medical equipment on-line. Our research found no statistically significant difference between the current CMS price and GSA price estimates for supplies.

4.5 Market Research Key Findings

Despite technological advances and inflation, the average Commercial Prices for medical equipment and supplies have remained relatively consistent with the current CMS prices that are based on historical invoices. Research indicated that discounted prices for supplies are often tied to contracts for negotiated equipment discounts, through service contracts and group purchasing organization contracts. These multi-year purchasing contracts may be an important factor in driving the price stability in the market for medical supplies.

The equipment market research did not indicate any statistically significant difference between the ‘averages’ of Current CMS Prices and the market research-based Commercial Prices. Likewise, the supply market research did not indicate any statistically significant difference between the ‘averages’ of Current CMS Price and the market research-based Commercial Price.

Although the averages and totals are similar, many of the Commercial Prices found were much higher than the Current CMS prices, which could indicate the impact of inflation, as many of the current prices are based on decades-old invoices. In contrast, the market researched Commercial Price estimates were much lower than the historical Current CMS prices for some pieces of equipment and supplies.

There are any number of reasons why some of the current CMS prices may be higher, for example, a) CMS prices may represent retail prices whereas the market research data collected represents net prices less discounts; b) actual prices may have decreased due to the lower cost of technology over the last decade; or c) market changes in response to bundled equipment and supply sales. Future research should include additional investigation into critical items where the market prices are materially lower than the historical current CMS Prices to better understand the drivers of change for appropriate pricing.

Unlike the Commercial Price, the research did indicate a statistically significant difference between the ‘averages’ of the Current CMS Price and the market-researched GSA Price for equipment but not for supplies. While the GSA Prices are designed to be the lowest available, the lack of data on GSA for many equipment codes may have impacted the results. The lack of data readily available on GSA may indicate that government providers typically use other contract vehicles to purchase discounted medical equipment. It may also reflect vendor reluctance to offer deeply discounted prices for medical equipment on-line. The vendor surveys indicated that vendors most frequently offer discounts through multi-year contracts such as group purchasing and service agreements.

For additional information, please refer to the spreadsheet format of this DPEI Market Research Report, as well as the following tables in spreadsheet format.

1. Attachment A – DPEI Report Attached Table A represents the research results with Current CMS Prices, the Recommended CMS Prices, and GSA Prices.
2. Attachment B – DPEI Report Attached Table B includes the Recommended CMS Price and four (4) alternative pricing models.

Recommended Price Formulas: A recommended price formula is presented for comparison with four alternative Price Options seen in Appendix C. Each Price Option, developed with CMS, provides alternative approaches to calculate pricing for CMS to use in the Proposed and Final Rules. The recommended price and all alternatives are most heavily based on the commercial price. The alternative Price Options differentiate from each other based on the impact of the commercial price and GSA.

5.0 Recommended CMS Price

An analysis of the market research data, statistical models, and health policy perspectives resulted in the following Recommended CMS Price for equipment and supply items. The Recommended CMS Price is the researched-commercial price, when available. If not, the recommended price is the current CMS price.

The senior statistician compared four other statistical models, Appendix C, including the integration of GSA pricing data. However, the statistician found the GSA pricing to be significantly different than both the current CMS and commercially researched prices. Therefore, it was ill-advised to integrate the GSA pricing into the Recommended CMS Price for equipment items. Likewise, for consistency, the GSA pricing for supplies is not integrated into the Recommended CMS Price for supply items. Due to these various factors, the Recommended CMS Price is the researched-commercial price (when available) or the current CMS Commercial Price when researched-commercial data is unavailable.

6.1 Post-Comment Responses

CMS received numerous comments related to the direct practice expense updates for medical equipment and supplies during the pre-comment period. StrategyGen reviewed all comments and performed a rigorous analysis of the topics and CMS codes identified in the comments. Each CMS Code discussed in the comment period was re-reviewed for accuracy and repriced if appropriate. To best respond to the comments' topics and CMS codes identified during the comment period, we aggregated the comments by their common themes and prepared a summary response for each theme. The following are the summary comments and responses.

6.2 Transparency

Comment:

Several commenters were concerned with the transparency of the data used to calculate medical equipment and supply prices. One concern of these commenters involved our use of a subscription-based benchmark database as a source for pricing data. The commenters stated that without identification of the database and access to the precise data used in determining the pricing update, they would have no systematic way to evaluate pricing accuracy. In addition, these commenters were concerned that small physician practices are not well represented in benchmark databases, with the consequence that the proposed repricing does not reflect the typical price paid by smaller stakeholders. A general concern is that any methodology that more heavily weighs larger physician groups, group purchasing organizations (GPOs), or even hospital contract pricing would result in pricing that is significantly depressed compared to the pricing that can be obtained by an individual practitioner. The commenters asserted that this has the potential to pressure the financial viability of smaller physician practices and to force lower cost non-facility procedures into hospital outpatient or inpatient sites of service.

Response:

We thank commenters for their feedback related to transparency and the potential effect of repricing on small physician practices. The commenters' question: 1) whether there is sufficient transparency to replicate and validate the proposed pricing, and 2) whether the proposed pricing is representative of prices available to small physician practices and non-facility practitioners.

As to whether there is sufficient transparency to enable others to replicate and validate the proposed pricing, we approved a market research plan designed to estimate the typical discounted prices that physicians and other providers normally pay. The proprietary database of buyer reported pricing is one of the few sources of typical discounted price data available. Other potential sources of typical discounted pricing were other proprietary databases and the publicly available GSA pricing. For each item priced, our analysis included research on as many as five current sources of prices: 1) a proprietary database of buyer reported pricing, 2) prices reported by GSA, 3) Amazon Business, 4) Cardinal Health, and 5) vendors' and manufacturers' catalogs.

The proprietary database of buyer reported pricing offers three advantages: 1) it represents discounted prices as opposed to retail pricing, 2) it has the largest sample sizes to represent a wider range of pricing as opposed single invoices, and 3) the database provides variety with respect to the purchaser's geographic location, purchasing method, procedure volume and other purchasing arrangements. We initially assumed that GSA also represents typical discounted pricing across regions with smaller sample sizes but subsequently rejected GSA data because its prices are not representative of commercially available pricing. Amazon Business and Cardinal Health represent typical retail pricing, with smaller sample sizes. In addition, we utilized vendors' and manufacturers' catalogs to identify publicly available pricing. Figure 13 summarizes sources of online pricing and characteristics of each source.

Source of Pricing Data	Discounted Pricing	Sample Size	Variety, (i.e., geography, purchasing arrangement, etc.)
Buyers database	Actual discounts	Largest	National footprint
GSA	Wholesale price	3-5	Government purchasers only
Amazon Business (on-line)	Retail price	3-5	National footprint
Cardinal Health (on-line)	Retail price	3-5	National footprint
Catalogs (on-line)	Retail price	3-5	National footprint

Figure 13: Sources of Online Pricing

The Buyers database provides the most accurate market pricing estimates that include market discounts for a range of buyer organizations. Its larger sample sizes provide more confidence that the proposed pricing is not skewed toward higher or lower pricing but toward the actual market price paid by purchasers.

We chose not to include invoice research in the market research plan as there is already an existing process to modify Direct Practice Expense Input prices based on invoices. Additionally, we determined that providing specific models and other identifying data with the researched prices would offer a broader and more consistent source of pricing data.

As to whether the proposed pricing is representative of prices available to small physician practices and non-facility practitioners generally, one of the objectives of the primary market research was to understand what kind of discounts are available to small physician practices similar to discounted pricing available to large health systems under GPOs.

The market research plan included a series of questions to vendors designed to illuminate typical discounts they offer to large and small providers other than GPOs. This market research indicates that there are a variety of discount purchasing options available. Vendors indicated that both volume and timing can influence pricing discounts. Approximately 80% of respondents indicated that timing has some impact on the price of equipment, and about half of respondents indicated that timing had some impact on the price of supplies. Discussions with other subject matter experts also indicated that timing

of purchase is an important factor in pricing. For example, the end of the sales cycle can drive discounts. Less than 10% of vendors indicated that these timing discounts may not be available to smaller practices outside of a GPO. The vendor research also indicated that ‘other’ factors beyond ‘size and timing’ influence discounted pricing.

Research indicates that Service Agreements often include discounts for equipment and supplies. For example, longer term Service Agreements generally result in larger discounts. However, some vendors indicated that the effect of Service Agreements was to reduce the size of the discounts, negatively impacting providers. This may be a difference in Service Agreement strategies across different vendors. Regardless, only three percent of respondents indicated that the availability of Service Agreement discounts was dependent on a GPO.

The vendors identified other factors that impact pricing decisions including:

- Market demand and competitive pricing;
- Contract renewal;
- Customer history and contract history; and
- Vendor considerations independent of the purchaser such as manufacturer and sales incentives, revenue goals, and new product releases.

In conclusion, while volume purchasing and GPOs drive down prices for many large providers, these are not the only drivers of discounts for providers. A number of additional factors applicable to large, small and non-facility practices may result in discounts for the buying organizations.

6.3 Prioritization of Equipment and Supplies

Comment:

Several commenters asserted that there is an inherent bias to prioritizing the medical equipment and supplies based on CMS spending and CMS Code utilization. These commenters stated that any attempt to accurately price items in the supply and equipment list should devote equal effort to each item of equipment or supply and should not devote additional attention to the most utilized CMS Codes. These commenters stated that using utilization data as the primary driver for identifying supply and equipment items to review suggests that there may have been specific intent to lower the cost of high utilization items, perhaps to the detriment of pricing accuracy. In addition, there was concern that some underutilized CMS Codes were not researched.

Response:

We thank these commenters for their feedback and for the opportunity to address this critical issue. To control for potential research bias, the market research team used an identical on-line methodology to research commercial pricing data for each of the supply and equipment codes, regardless of the code’s prioritization. The CMS prioritization of high-utilization supply and equipment codes was not designed

to reduce their prices.

The CMS prioritization of supply and equipment codes was designed to facilitate understanding and validation of the researched commercial prices for these items. Surveying other market entities, including vendors, as opposed to buyers, was used to more precisely identify the range of commercial pricing and factors impacting those prices. For example, additional priority research included a physician panel that reviewed the researched commercial prices for reasonableness. The prioritization of research for certain codes did not change the recommended commercial prices.

In addition, limited time and resources required prioritizing the codes based on use. We recognize that a few medical supply and equipment codes do not have updated recommended prices, and we continue to welcome the submission of updated pricing information from stakeholders for these and other codes.

6.4 Alternative Pricing Options

Comment:

Some commenters were concerned that the researched GSA price was incorporated into the recommended commercial price. These commenters expressed concern as to how the GSA price fit into the calculation of new recommended prices.

Response:

We thank the commenters for their feedback and this opportunity to clarify if the GSA price was used in developing the new recommended DPEI prices for equipment and supplies. The GSA price was not used to calculate final recommended prices. Our use of the GSA website to research supply and equipment pricing was found to have a number of limitations. Only suppliers that meet stringent qualifications and that complete a lengthy and detailed application process are eligible to participate in GSA Advantage, GSA's online shopping and ordering system. These requirements sharply curtail the number and type of suppliers whose products may be accessed on the GSA Advantage website. In addition, only products that are purchased by federal agencies or other qualified government entities are listed on the GSA Advantage website, which has the effect of eliminating a number of medical supplies and equipment that are covered by CMS DPEI codes. This limitation was especially acute when researching bundled codes for equipment rooms and lanes, and supply packs, kits, and trays. The GSA website does not record comparable bundled purchasing of medical equipment or supplies, so no GSA pricing could be recovered for products included in the bundled codes organized as rooms, lanes, packs, kits or trays. Finally, the prices listed on the GSA Advantage website are required to be the supplier's best offer which may often be lower than prices that are available to non-governmental purchasers.

For these reasons, the GSA price was not incorporated into the calculation for the final recommended price. The final recommended price for 2019 was the commercially researched price, if available. Otherwise the current 2018 CMS price remained in place as the 2019 CMS price.

6.5 Research Methodology

Comment:

Several commenters were concerned with the methodology used to conduct market research to determine an updated price for medical equipment and supplies. There were significant concerns with the use of market research to supplement the current AMA/Specialty Society RVS Update Committee process.

Response:

CMS determined that the most effective way to update the DPEI for FY2019 was through comprehensive market research. The current RUC process has resulted in updates to many of the equipment and supply codes, but many of the prices in the FY2018 DPEI are over a decade old, and a significant number date back to research conducted fifteen years ago. Therefore, CMS requested a market research plan designed to research current pricing to estimate the typical discounted prices that physicians and other providers normally pay.

The comprehensive market research plan to update DPEI equipment and supplies was designed to supplement the AMA RUC process, not replace it. The current RUC process, while indispensable, does not provide for comprehensive pricing updates. Under the current process, physicians and other providers voluntarily submit invoices for items to RUC for consideration, and after review, RUC submits these invoices to CMS. This process results in inherent biases due to the limited number of items represented by submitted invoices and due to the voluntary selection of reported invoices.

The market research plan examined up to five online sources of current prices for each item of equipment or supply researched, including: 1) a proprietary database of buyer reported pricing, 2) prices offered on GSA (subsequently excluded from the recommended 2019 CMS prices), 3) Amazon Business, 4) Cardinal Health, and 5) vendors' and manufacturers' catalogs. Each of these sources is contains nationally reported vendor and buyer pricing data. The effect of regional pricing differences for reimbursements is included through the Relative Value Units modifiers. The research plan also included vendor interviews to clarify the variety of discount programs available to physicians and other providers.

The comprehensive research plan for the 2019 DPEI required researching approximately 2,000 supply and equipment codes. Qualitative and potentially quantitative research to include all the specialty societies impacted by the DPEI updates was beyond the resources and time allocated to the 2018 update. The market research plan did include a physician panel with specialists and a general practitioner to review the reasonableness of the researched data. In addition, the regulatory process remains available to all specialty societies to comment on the recommended prices.

6.6 Components Repricing

Comment:

Many commenters addressed the proper pricing of some multi-component items, including supply kits, packs, and trays as well as some items of equipment. Several commenters noted some of the recommended prices proposed for items of equipment and supplies that contain multiple components may not accurately reflect all the components, while other commentators noted some of the components could be improperly priced. Commenters expressed concerns that some equipment may not possess precise components that are necessary for a specific procedure.

Response:

We thank the commenters that identified possible inaccuracies in the inclusion and/or pricing of multi-component items. Using the information provided by these commenters, we re-examined the pricing of the multi-component items of equipment and supplies identified. In some instances, our additional research confirmed some commenters' concerns, as we found that a limited set of these multi-item supply and equipment kits required further clarification of components. For example, an item within a multi-kit, pack, or tray may have had an updated component, resulting in a mispriced item within that kit. To further clarify the prices of these kits, the kits were broken into their most basic components and priced individually. The total price of the kit was determined by adding the specific item prices together. If one of the items within a kit was misidentified, it resulted in an incorrect price of the entire kit.

For example, a review of the recommended price for CMS Code SH007 - "Antigens, multi," identified the need to add pricing data for additional antigens and to refine the unit of measurement used in calculating the price. For SH007 additional antigens were added and data analyzed for 1 milliliter vials of two allergy antigens. The first antigen is an allergy antigen for pollen and mites and contains antigens for Timothy, Birch, Ragweed, Cocklebur, MarshElde, and the mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farina*. The second antigen is an allergy antigen for mold and cats and contains antigens for Alternaria, Helminth, Hormoden, Penicillium, and Fel d1. To determine the price of the allergy antigen, we researched each component of the antigen separately and averaged the price of the separate vials as the recommended price.

In instances related to equipment, an item may have been improperly priced because a specific component was omitted but the items priced could perform the requisite task. An example of this occurred in the pricing of ER083 - "SRS System, SBRT," where the equipment priced would retrofit a system to perform SBRT procedures, but pricing did not include the linear accelerator. When re-examining this specific medical equipment, we ensured it was a linear accelerator with SBRT capabilities.

We re-examined the recommended price of each multi-component item cited by a commenter. Figure 14 details price changes based on comments received and our resulting additional price research:

CMS Code	Description	2018 CMS Price	2019 CMS Price
SA122	ClariVein Kit	\$890.00	\$883.33
SH007	Antigen, multi	\$6.70	\$8.96
ER083	SRS System, SBRT	\$4,000,000.00	\$2,973,721.84
SA026	Kit, radiofrequency introducer	\$50.00	\$24.16
SA074	Kit, endovascular laser treatment	\$519.00	\$323.33
SA100	Kit, probe, radiofrequency, Xlienanced RF probe	\$2,695.00	\$1,966.67
SA106	Balloon Sinus Surgery Kit	\$2,599.86	\$2,374.33
SA099	Kit, probe, cryoablation, prostate (Galil-Endocare)	\$4,700.00	\$1,539.56
EP014	Flow cytometer	\$119,850.00	\$192,000.00
EP088	ThermoBrite	\$6,120.00	\$4,795.00
EP116	VP-2000 Processor	\$30,800.00	\$37,993.00
SA105	Urovysion test kit	\$176.80	\$129.28
SL261	FISH pre-treatment kit	\$549.00	\$579.21
SL488	UltraView Universal DAB Detection Kit	\$10.49	\$9.70
SL498	Kappa Probe Cocktail	\$0.10	\$0.91
ER003	HDR Afterload System, Nucletron Oldelft	\$375,000.00	\$132,574.78
ED033	Treatment planning system, IMRT	\$350,545.00	\$197,247.00
EF031	Table, power	\$6,153.63	\$5,906.76
EQ288	Ultrasonic cleaning unit	\$895.00	\$895.00
EQ343	Radioaerosol Administration System	\$2,560.25	\$623.00

Figure 14: Update based on Components

6.7 Quantity Repricing

Comment:

Several commenters questioned the prices of certain supply codes based on their conclusion that the quantity of the items priced was inaccurate. Depending on the type of supply, a number of different units of measurement are used to set prices for DPEI supply codes. Figure 15 shows the codes that were cited by commenters as being potentially mispriced based on possibly inaccurate quantities.

Response:

We thank the commenters that brought possible clarifications in the quantity of the items priced to our attention. In each instance in which a commenter questioned the accuracy of a DPEI code's recommended price based on a concern about the quantity of the item priced, we conducted further

research of the item and its price with special attention to ensuring that the recommended price was based on the clarified unit of measure. The price assigned to a given code may be for a single item, a kit, a tray, or it may be based on a per test or per ml basis. For example, the price for SG055 is for a single sterile 4in x 4in gauze sponge; whereas the price for SG056 is for a tray/pack of 10 sterile 4in x 4in gauze sponges. In other situations, such as SL060 – “Embedding Mold,” the price for a package of multiple molds were reported instead of the price of a single embedding mold. After consideration of comments received and additional price research, we have updated the recommended prices for the relevant codes in Figure 15 as follows:

CMS Code	Description	2018 CMS Price	2019 CMS Price
SL191	Ethanol, 85%	\$0.003	\$0.02
SL497	(EBER) DNA Probe Cocktail	\$8.57	\$8.19
SL060	Embedding Mold	\$0.15	\$0.12
SL493	Antibody Estrogen Receptor monoclonal	\$14.47	\$16.12
SL012	Antibody IgA FITC	\$41.18	\$30.03
SG055	Gauze, sterile 4in x 4in	\$0.16	\$0.19
SG056	Gauze, Sterile 4in x4in (10 pack uou)	\$0.80	\$1.20
SJ055	Test strip, INR	\$5.66	\$4.71
SL258	Control slides	\$228.00	\$203.73
SL474	Confirm anti-CD15 Mouse Monoclonal Antibody (Ventana 760-2504)	\$3.61	\$3.82
SL483	Hematoxylin II (Ventana 790-2208)	\$0.02	\$0.78
SL484	Bluing reagent (Ventana 760-2037)	\$4.52	\$0.45
SB026	Patient gown	\$0.53	\$0.59
SA081	Pack, drapes, ortho, small	\$1.13	\$2.25
SH009	Antigens	\$20.14	\$30.93
SH010	Antigens	\$44.05	\$60.24
SB019	Towels / Drape-towel, sterile 18in x 26in	\$0.28	\$0.47

Figure 15: Update based on Quantity

6.7 Price Re-Examination

Comment:

Several commenters addressed the subject of the proper pricing for certain items of medical supply and equipment. These commenters requested these specific CMS codes be reviewed again to ensure the correct items were being researched and priced accordingly.

Response:

We thank commenters for their feedback. Based on their requests, we conducted an extensive examination of the pricing of all items of equipment or supply that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified codes for accuracy and proper pricing. In most cases, we also reached out to our team of nurses and our physician panel to further validate the accuracy of the data and pricing information. In some cases, priced items needed further clarification due to a lack of information or significant variation in packaged items. An example of such clarification occurred with SD254 - “Covered Stent (Viabahn, Gore),” which encompasses a wide range of stents, with varying sizes and other qualities. In other cases, such as EQ340 - “Patient Worn Telemetry System,” an inpatient unit was originally priced as opposed to an outpatient unit. After an extensive review and validation process, we updated our recommended prices for the CMS codes in Figure 16, below:

CMS Code	Description	2018 CMS Price	2019 CMS Price
EQ340	Patient Worn Telemetry System	\$23,537.00	\$23,494.00
EQ312	INR analysis and reporting system w-software	\$21,085.00	\$19,325.00
EQ031	INR monitor, home	\$2,000.00	\$635.00
SD254	Covered stent (VIABAHN, Gore)	\$3,768.00	\$3,129.00
SD114	Sensor, glucose monitoring (interstitial)	\$29.50	\$59.31
EQ125	Glucose continuous monitoring system	\$1,170.54	\$850.00
SD155	Catheter, RF endovenous occlusion	\$725.00	\$550.00
SD109	Probe, radiofrequency, 3 array (StarBurstSDE)	\$353.64	\$2,289.00
SD253	Atherectomy device	\$4,979.67	\$3,048.33
SD304	IVUS catheter	\$1,025.00	\$858.33
SD250	Introducer sheath, Ansel	\$90.00	\$72.64
EQ370	Breast Biopsy Software	No current CMS Price	\$43,308.12
SD255	Reentry device	No current CMS Price	\$2,343.12
SD251	Sheath shuttle	No current CMS Price	\$109.69
SD134	Non-latex (6ft) tubing, suction with Yankauer tip	\$2.96	\$2.67
SF040	Vicryl suture	\$7.85	\$8.52
SL182	Mounting media (DAPI II counterstain)	\$67.00	\$54.00
SL185	Slide, positive control, HER-2	\$29.40	\$26.20
SL196	HER-2/neu DNA probe	\$105.00	\$79.05
ES052	Brachytherapy Treatment Vault	\$175,000.00	\$193,114.25

Figure 16: Update based on Price Re-examination

6.8 Pricing Remains Unchanged

Comment:

Several commenters expressed concerns regarding the proposed prices for the equipment and supplies listed below in Figure 17 and recommended the price remains unchanged until additional research can be conducted.

Response:

We investigated the accuracy of components or features included in an item by researching the identity of the item based on the CMS description contained in the item's DPEI codes, as well as the identity of any items prices in submitted invoices. Additional research into the items set forth in Figure 17 failed to produce reliable product data sufficient to calculate a recommended price. To price these equipment and supply items accurately, we believe additional information is required. Therefore, we will continue to use the current CMS price for these equipment and supply items pending additional research and analysis. We welcome the submission of updated pricing information regarding these equipment and supply items through submission of valid invoices from commenters and other stakeholders.

CMS Code	Description	2018 CMS Price	2019 CMS Price
EL016	Room - Ultrasound, vascular	\$466,492.00	\$466,492.00
EL015	Room - Ultrasound, general	\$369,945.00	\$369,945.00
SA117	Universal Detection Kit	\$4.00	\$4.00
SL184	Slide, negative control, HER-2	\$29.40	\$29.40
SL195	Kit, FISH paraffin pre-treatment	\$20.85	\$20.85

Figure 17: Price Remains Unchanged

7.0 Appendices and Attachments

Appendix A: Tables

Table E: Equipment Summary

Equipment Summary	Total	Category Description
1. Room – Lane	29	Each of these equipment codes refers to a bundle of equipment items that are commonly used to provide a specific service.
2. Documentation	46	These equipment codes include computers, printers, cameras, and software used to record and document procedures.
3. Furniture	44	These equipment codes include different types of chairs, exam tables, and other furniture that is found in medical facilities. It includes specialized furniture intended for use in clinical environments, as well as generic items of furniture.
4. Imaging (all)	99	This broad category includes all imaging equipment used for diagnostic and treatment purposes, such as x-ray equipment, MRI and CT scanners, and IMRTs.
5. Laboratory	104	These equipment codes include items used in a medical laboratory such as an incubator, centrifuge, and microscopes.
6. Other Equipment	374	This catchall category contains equipment items that do not fit into any other specific category.
7. Scope	47	These equipment codes include different types of scopes such as endoscopes and ultrasound probes.
8. Not Researched to Completion	8	These equipment codes were not researched to completion because there was not enough available data to identify the equipment item.
Total:	751	

Table F: Supply Summary

Supply Category	Count	Category Description
1. Kit, Pack, Tray	117	Each of these supply codes includes multiple supply items that are commonly used in combination to provide a specific service.
2. Accessory, Procedure	290	These supply codes include different parts of catheters, electrodes, tubes, and sensors to for specific equipment.
3. Cutters, Closures, Cautery	57	This category includes different types of sutures, wires, and blades.
4. Gown, Drape	51	These supply codes include gowns, drapes, and also include protective equipment such as caps and safety glasses.
5. Hypodermic, IV	93	These are different types of syringes, needles, and tubing.
6. Infection Control	26	This category includes supplies to contain biohazards and items used to for disinfection such as wipes, lotions, and other sanitizing supplies.
7. Lab	310	Supplies in this category would generally be found in a laboratory.
8. Office Supply, Grocery	92	These supplies include typical office supplies and other non-medical items, such as paper towels.
9. Pharmacy, NonRx	89	These supplies are non-prescription medications.
10. Pharmacy, Rx	96	These supplies are prescription medications.
11. Wound Care, Dressings	95	These medical supplies are generally used to dress, splint, or bandage a wound.
12. Imaging Equipment	1	This imaging tray is the only supply item in this category and does not fit within any other supply category.
13. Not Researched to Completion	4	These supply codes were not researched to completion because there was not enough information to identify the supply item.
Total:	1,321	

Table G: Vendor Survey Equipment Prices

Prices Reported by Purchaser Size		Room MRI (11)	Room ultrasound vascular (8)	Room CT (12)	IMRT accelerator (4)	Patient-worn telemetry system (6)	Room angiography (6)	Room basic radiology (8)
Lowest	Large	\$38,000	\$7,000	\$21,000	\$7,500	\$40,000	\$175,000	\$78,000
	Medium	\$11,000	\$5,000	\$22,500	\$7,500	\$40,000	\$200,000	\$50,000
	Small	\$12,500	\$25,000	\$21,000	\$7,500	\$40,000	\$55,000	\$25,000
Highest	Large	\$750,000	\$29,000	\$250,000	\$7,500	\$60,000	\$175,000	\$200,000
	Medium	\$750,000	\$29,000	\$250,000	\$7,500	\$60,000	\$200,000	\$180,000
	Small	\$750,000	\$29,000	\$250,000	\$7,500	\$60,000	\$55,000	\$160,000
Average	Large	\$345,500	\$20,300	\$181,800	\$7,500	\$50,000	\$175,000	\$126,000
	Medium	\$310,500	\$19,700	\$165,400	\$7,500	\$48,300	\$200,000	\$102,700
	Small	\$227,900	\$27,000	\$119,800	\$7,500	\$46,700	\$55,000	\$87,700

Table H: Vendor Survey Equipment Prices

Prices Reported by Purchaser Size		Room ultrasound general (17, 16, 17)	Radiation virtual simulation system (4)	Radiation treatment vault (2)	Lane OPH screening (14)	Room radiographic-fluoroscopic (6)	Attended sleep diagnostic system (4)	Lane OPH exam (7, 7, 8)
Lowest	Large	\$5,000	\$25,000	None	\$6,400	\$150,000	None	\$8,000
	Medium	\$5,000	\$27,500	None	\$6,400	\$175,000	None	\$8,000
	Small	\$5,000	\$27,000	None	\$6,400	\$280,000	None	\$8,000
Highest	Large	\$750,000	\$25,000	None	\$60,000	\$350,000	None	\$60,000
	Medium	\$750,000	\$27,500	None	\$60,000	\$300,000	None	\$60,000
	Small	\$750,000	\$27,000	None	\$60,000	\$300,000	None	\$60,000
Average	Large	\$105,100	\$25,000	None	\$27,400	\$266,700	None	\$34,000
	Medium	\$132,600	\$27,500	None	\$29,000	\$258,300	None	\$39,300
	Small	\$114,200	\$27,000	None	\$27,900	\$290,000	None	\$34,500

Table I: Vendor Survey Equipment Discounts

Prices Reported by Purchaser Size		Room MRI (11)	Room ultrasound vascular (8)	Room CT (12)	IMRT accelerator (4)	Patient-worn telemetry system (6)	Room angiography (6)	Room basic radiology (8)
Lowest	Large	5%	5%	5%	5%	0%	5%	5%
	Medium	0%	5%	0%	5%	0%	0%	5%
	Small	0%	5%	0%	5%	0%	0%	5%
Highest	Large	45%	25%	25%	35%	25%	15%	35%
	Medium	45%	25%	25%	35%	25%	15%	25%
	Small	45%	25%	25%	35%	25%	5%	25%
Average	Large	20%	20%	16%	18%	15%	12%	19%
	Medium	18%	16%	13%	15%	13%	7%	14%
	Small	18%	15%	13%	14%	10%	4%	10%

Table J: Vendor Survey Equipment Discounts

Prices Reported by Purchaser Size		Room ultrasound general (17, 16, 17)	Radiation virtual simulation system (4)	Radiation treatment vault (2)	Lane OPH screening (14)	Room radiographic-fluoroscopic (6)	Attended sleep diagnostic system (4)	Lane OPH exam (7, 7, 8)
Lowest	Large	5%	5%	5%	0%	5%	15%	0%
	Medium	5%	0%	5%	0%	0%	5%	0%
	Small	5%	0%	4%	0%	0%	15%	0%
Highest	Large	25%	15%	15%	25%	35%	25%	15%
	Medium	25%	15%	15%	25%	45%	25%	15%
	Small	25%	5%	9%	25%	25%	25%	15%
Average	Large	19%	14%	13%	6%	16%	22%	9%
	Medium	14%	8%	10%	13%	15%	14%	8%
	Small	12%	3%	7%	10%	8%	20%	7%

Table K: Vendor Survey Supply Prices

Prices Reported by Purchaser Size		Flexible stent-graft (7)	Balloon catheter for low-profile PTA (10)	6-0 vicryl suture (10)	LMX 4% topical anesthetic (10)	Emboloc protection devices (7)	Balloon catheter for PTA (11)	6-inch wide therabands (13)
Average	Large	\$3,500	\$3,000	\$10	\$8	\$1,700	\$600	\$15
	Medium	\$3,500	\$3,000	\$10	\$11	\$1,700	\$700	\$12
	Small	\$3,500	\$3,000	\$10	\$13	\$1,700	\$1000	\$12

Table L: Vendor Survey Supply Prices

Prices Reported by Purchaser Size		Gelfoam dressing 12-7 mm. (11)	Mite antigen (7)	UltraView universal DAB detection kit (1)	Staff gown impervious to liquids (13)	Sterile gloves (18)	1-inch elastic, water-repellent tape (14)	UroVysion molecular test kit (3)
Average	Large	\$20	\$100	\$150	\$6	\$0.05	\$12	\$400
	Medium	\$20	\$100	\$150	\$8	\$0.05	\$12	\$400
	Small	\$19.80	\$100	\$150	\$3	\$0.05	\$12	\$400

Table M: Vendor Survey Supply Discounts

Prices Reported by Purchaser Size		Flexible stent-graft (7)	Balloon catheter for low-profile PTA (10)	6-0 vicryl suture (10)	LMX 4% topical anesthetic (10)	Emboloc protection devices (7)	Balloon catheter for PTA (11)	6-inch wide therabands (13)
Lowest	Large	5%	5%	3%	3%	5%	5%	3%
	Medium	5%	5%	3%	3%	5%	5%	3%
	Small	3%	5%	3%	3%	0%	3%	0%
Highest	Large	50%	55%	60%	36%	40%	50%	25%
	Medium	50%	50%	50%	23%	30%	50%	40%
	Small	50%	50%	40%	15%	30%	50%	20%
Average	Large	25.13%	25.58%	26.58%	14.1%	20%	26.79%	13.91%
	Medium	20.89%	22.92%	21.83%	10.1%	16.88%	21.33%	14.83%
	Small	16.67%	19.17%	14%	7.9%	15.63%	17.87%	8.45%

Table N: Vendor Survey Supply Discounts

Prices Reported by Purchaser Size		Gelfoam dressing 12-7 mm. (11)	Mite antigen (7)	UltraView universal DAB detection kit (1)	Staff gown impervious to liquids (13)	Sterile gloves (18)	1-inch elastic, water-repellent tape (14)	UroVysion molecular test kit (3)
Lowest	Large	3%	0%	15%	7%	0%	3%	10%
	Medium	3%	0%	15%	5%	0%	3%	10%
	Small	5%	0%	5%	4%	0%	3%	10%
Highest	Large	50%	50%	36%	50%	75%	50%	30%
	Medium	50%	30%	23%	50%	60%	50%	20%
	Small	45%	20%	15%	50%	50%	50%	15%
Average	Large	21.31%	20.71%	23.67%	26.93%	25.27%	21.25%	18.33%
	Medium	17.56%	16%	19.33%	24%	20.83%	18.25%	15%
	Small	16.25%	11.43%	10.67%	17.07%	13.36%	15.95%	12.5%

Appendix B: Overview of Medicare's RVU Reimbursement System

Prior to 1992, the Medicare Program reimbursed physicians using a customary, prevailing, and reasonable payment system. This system was based on physicians' "reasonable charges" for their services, which was defined as (1) the physician's actual charge; (2) the physician's customary charge, or (3) the prevailing charge, defined as the 75th percentile charged by specialty-specific physicians within a Medicare payment area. The reasonable charge system had a number of weaknesses. Fee variations arose over time across different geographic areas of the country. Different payment rates for the same service developed, with variations often depending on the specialty of the physician providing the service. By tying the level of reimbursement directly to the amount charged, the structure of the payment calculations incentivized physicians to increase their charges. The system failed to impose any connection between the amount of reimbursement paid by CMS for a given service and the resources utilized or the costs incurred to furnish that service.

The Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101-239] and the Omnibus Budget Reconciliation Act of 1990 [Pub. L. 101-508], established the Medicare Physician Fee Schedule, which decoupled Medicare reimbursement from physician charges for services. Instead of basing reimbursement on what physicians charged for a service, the statute required reimbursement to be based on the value of the resources utilized to deliver the service. To develop a new payment methodology, the Health Care Financing Administration ("HCFA") contracted with the Harvard School of Public Health to develop a system of physician reimbursement based on the value of the resources consumed in providing services.

The resulting compensation system bases payments on a resource based relative value scale that ties payment to value of the resources consumed in providing a service. Four value inputs are considered in determining the reimbursement payable by Medicare under the PFS for a given service: physician work; malpractice expense, direct practice expense, and indirect practice expense. The weight of each input is expressed in the context of "relative value units" (RVUs).

The physician work component (wRVU) considers the physician's expertise, physical effort, and the time and technical skill spent in performing the coded service, including the mental effort, psychological stress (associated with the severity of the possible adverse patient outcomes) and judgment expended by the physician prior to, during and after the patient encounter terminates, including documentation of the service.

The American Medical Association ("AMA") sponsors the Specialty Society Relative Value Scale Update Committee ("RUC"), which advises CMS on the developing physician wRVU values for new and revised CPT codes. The RUC is composed of 31 members. Twenty-one major national medical specialty societies (e.g., cardiology, dermatology, general surgery) each appoint one

member, with the goal of capturing the combined expertise of the major American medical specialties. The RUC develops wRVU recommendations for new CPT codes on an annual basis and reviews all physician wRVU codes for existing CPT codes as part of the required Medicare five-year review cycle.

The professional liability component (MP RVU) assigned to a given service accounts for the proportional cost of professional liability expense represented by that service. When the PFS was initially established, malpractice RVUs continued to be based on historic charges. In 2000, the malpractice RVU was revised to determine its value using a resource-based system. The MP RVU component is based on the national average premium for malpractice insurance for each physician specialty and the specialty's risk factor (determined by dividing the national average premium for a given specialty by the national average premium for the specialty performing that service with the lowest average premium). This specialty-weighted approach allows the malpractice RVU for a service to be based on the weighted average of the risk factors for all specialties commonly performing that service.

The RVU value for practice expenses (PE RVU) is composed of two types of practice expense: direct practice expense and indirect practice expense. Direct practice expenses consist of the costs of equipment, medical supplies, and clinical and administrative staff directly utilized in providing a particular service for a patient office. The indirect expense category seeks to account for the costs of items and services that are necessary to operate a medical practice but that are not directly consumed in providing a given service. Indirect practice expenses include, but are not limited to, the costs of rent, office equipment, utilities, and administrative personnel.

Initially, PE RVUs (like MP RVUs) were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103-432), amended section 1848(c)(2)(C)(ii) of the Act and required CMS to develop resource-based PE RVUs for each physicians' service beginning in 1998. CMS was required to assign RVUs to general categories of expenses, such as office rent and wages of personnel, comprising practice expenses. Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105-33) ("BBA") delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs, which further delayed the full implementation of the PE RVU compensation component.

CMS published a final rule on November 4, 1998 (63 FR 58814) governing PE RVUs. It established resource-based PE RVUs for each physician service and became effective for services furnished beginning in 1999. Based on the requirement to transition from a charge-based PE RVU system to a resource-based system over a four-year period, payment rates fully based upon

resource-based PE RVUs were not completely phased in until CY 2002. This resource-based system used two major sources to acquire practice expense data: The Clinical Practice Expert Panel (“CPEP”) data; and the AMA’s Socioeconomic Monitoring System (“SMS”) data. These data sources are described in greater detail in the CY 2002 Final Rule (76 FR 73033).

Appendix C: Statistical Pricing Model Analysis

The senior statistician analyzed four other statistical pricing models to substantiate the Recommended CMS Price. The pricing models were developed with input from CMS and provided alternative approaches to calculate pricing for equipment and supply items. The statistician found the GSA pricing to be significantly different than both the current CMS and researched prices. Based on the results of our test, we developed a recommended price as well as additional optional prices based on different models. The recommended model and the various optional tested models are further described below.

Recommended CMS Price: This recommended price is the researched-commercial price, when available. If not, the recommended price is the current CMS price.

The senior statistician found no statically significant difference among these pricing alternatives, described below. The statistician found the GSA pricing to be significantly different than both the current CMS and commercially researched prices. Therefore, it was ill-advised to integrate the GSA price into the Recommended CMS Price for equipment items. In addition, the options that most heavily integrate GSA pricing, relative to commercial pricing, tended to result in the lowest prices. For consistency, the GSA prices are not integrated into the Recommended CMS Price for supply items.

The following describes the four options that were evaluated for the recommended CMS price.

1. **OPTION 1:** The researched commercial price, when available. If not available, then the GSA price. If the GSA price is also unavailable, then the current CMS Price.
2. **OPTION 2:** The researched commercial price and GSA price, *weighted by sample size*. If commercial price is not available, then the GSA price. If the GSA is unavailable, then the commercial price. If neither are available, the price is the current CMS price.
3. **OPTION 3:** A weighted average of the commercial price (unweighted average regardless of sample size) and GSA price, weighted by a statistical factor to increase the impact of GSA results. If commercial price is not available, then the GSA price. If the GSA is unavailable, then the commercial price. If neither are available, the price is the current CMS price.

In Option 3, the statistical factor used was the regression coefficients from the linear regression model using the CMS-Price as the dependent variable and both GSA and Commercial Price as the independent variables.

Equipment: The parameter estimates from the model is 0.93 for average commercial price and 0.21 for average GSA price (*R-Square=0.81*). Therefore, under the Option 3 Model:

$$\text{Price} = 0.93 * \text{Commercial Price} + 0.21 * \text{GSA Price}$$

Supplies: The parameter estimates from the model is -0.09 for average commercial price and 1.25 for average GSA price ($R\text{-Square}=0.96$). Therefore, under the Option 3 Model:

$$\text{Price} = -0.09 * \text{Commercial Price} + 1.25 * \text{GSA Price}$$

4. **OPTION 4:** Commercial price, unweighted average regardless of the sample size. If commercial price is not available, then the GSA price. If the GSA is unavailable, then the commercial price. If neither are available, the price is the current CMS price.

Option 4 was based on a formula that always included the GSA research in order to harvest the largest available sample sizes. However, as the research indicated many of the GSA prices are significantly different for equipment, which skewed this model as well as the others that integrated GSA prices.

As stated, no significant difference was found among (1) the current CMS price, (2) the recommended CMS price, and (3) the four alternative pricing models. In the following table, the total price is defined as the sum of prices as defined under each model for the top 50 CMS codes. CMS identified the top 50 codes by total annual cost, a product of utilization and current CMS price. These totals represent the approximate impact to CMS under these different models.

Price Models	Sample Size	Equipment Total Price	Supplies Total Price
Current CMS Price	50	\$17,660,675.09	\$22,488.49
Recommended Price	50	\$14203132.84	\$17765.23
Option 1	50	\$14185751.18	\$17765.23
Option 2	50	\$17110594.25	\$18516.27
Option 3	50	\$13156265.98	\$20969.42
Option 4	50	\$13139527.39	\$17557.09

Attachment B contains the recommended CMS price as well as the four alternative pricing options for review.

Appendix D: References

1. AMA/Specialty Society RVS Update Process RUC Recommendations for CPT 2017 Introductory Materials, American Medical Association, February 2016, accessed at <https://www.ama-assn.org/sites/default/files/media-browser/february-2016-ruc-recommendations.pdf>.
2. Medical Equipment & Supplies Industry Profitability, accessed at https://csimarket.com/Industry/Industry_Profitability
3. Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology, 71 FR 37169 (June 6, 2006).
4. Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010, 74 FR 61737 (November 25, 2009).
5. Physician and Other Health Professional Payment System, Medicare Payment Advisory Commission, October 2017, accessed at http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_physician_final.pdf?sfvrsn=0%20
6. Report to the Congress: Medicare and the Health Care Delivery System, Medicare Payment Advisory Commission, June 2017.
7. Sanaz Hariri *et al*, “Medicare Physician Reimbursement: Past, Present and Future, Journal of Bone and Joint Surgery, 2007; 89:2536-46.

Attachments

Spreadsheets

Attachment A – DPEI Report Attached Table A

- Research results with Current CMS Prices, the Recommended CMS Prices, and GSA Prices.

Attachment B – DPEI Report Attached Table B

- Recommended CMS Prices and four (4) alternative pricing models.

Report

Attachment C – Final Market Research Plan 16 Oct 17